Parascript® *Accu*Detect® CAD Software System

Computer Aided Detection for Digital Mammography

USER MANUAL

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PARASCRIPT®

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4 Parascript® AccuDetect® in Breast Cancer Detection

4.1 Overview

Parascript® *Accu*Detect® is a Computer-Aided Detection (CAD) software device intended to aid radiologists reading mammograms. It is a proprietary software application designed to process digital images. The digital mammography images are automatically analyzed to identify areas suspicious for possible soft tissue densities and/or calcifications.

4.2 Installation

The Parascript® *Accu*Detect system consists of proprietary software and general-purpose computing equipment. The device is delivered as an integrated system with specific installation configuration.

The *Accu*Detect CAD software is installed on off-the-shelf computing equipment (see below) by trained technicians, using documented installation procedures and instructions.

Figure 1 illustrates the Parascript® AccuDetect System in context of hospital infrastructure:

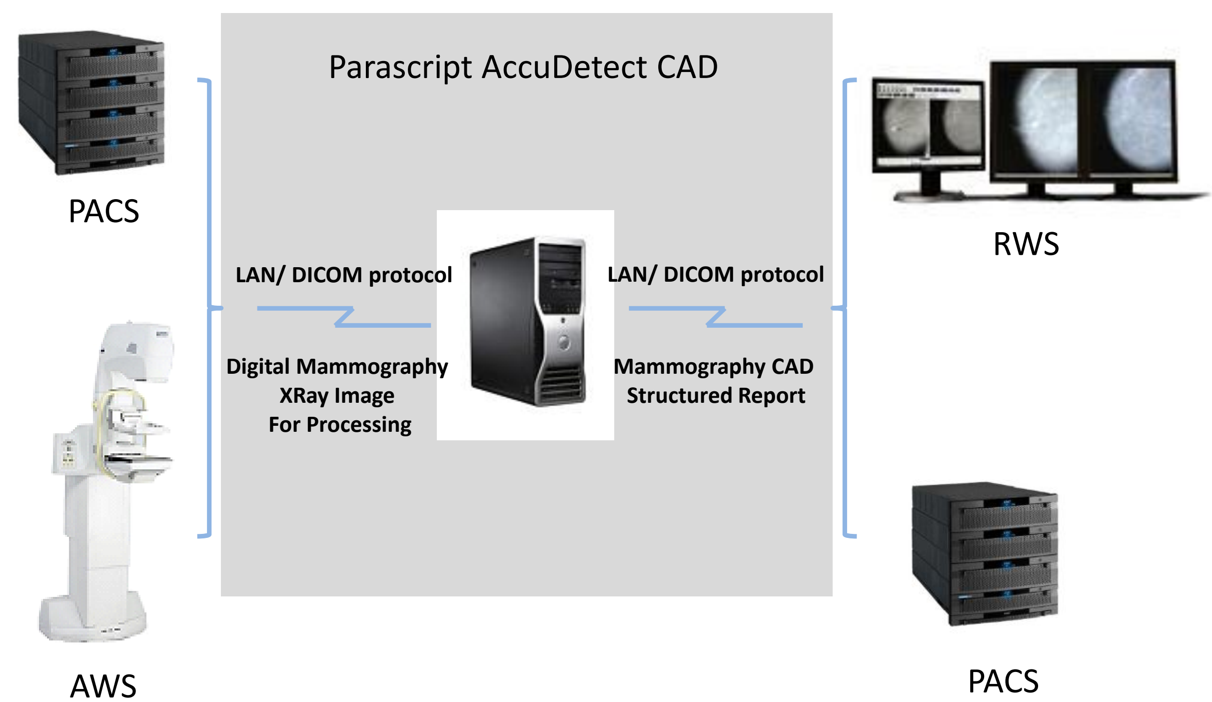


Figure 1. Parascript® AccuDetect System in Context of Hospital Infrastructure

The Parascript *Accu*Detect system is intended to work on a standalone computer and communicates with input and output devices through LAN via DICOM 3.0 protocol.

The Parascript *Accu*Detect system receives input images from the Acquisition Workstation (AWS), Picture Archiving and Communication System (PACS) or other enabled storage device via DICOM interface. The *Accu*Detect CAD software processes digital images created by GE Senographe (Essential, DS, and Care) or Philips MicroDose Full Field Digital Mammography Systems (FFDMs).

The *Accu*Detect results are sent in the form of a DICOM Mammography CAD Structured Report (SR) to a Review Workstation (RWS) and/or PACS.

4.3 Description of Parascript® *Accu*Detect®

*Accu*Detect® is a mammography CAD system that identifies potential areas of concern to assist radiologists in breast cancer detection. The CAD algorithms used in the *Accu*Detect® computer system include image processing, feature computations, and pattern recognition technology to detect mammographic features indicative of malignancies. Results are displayed on a computer monitor for review by a radiologist.
For each mammogram, a radiologist is instructed to first review each case in the conventional manner and then re-examine the case utilizing the information supplied by the Parascript® *Accu*Detect system before making a final assessment for the case. Reviewing *Accu*Detect CAD results prior to the initial unassisted review of the mammogram could cause the radiologist to fail to examine the unmarked areas with adequate care.
*Accu*Detect® is designed to identify areas with the mammographic appearance of cancer; however, many of the identified areas will not contain a malignancy, and it is up to the radiologist to decide, using conventional clinical judgment and reviewing the mammogram itself, if the area is suspicious enough to warrant further work-up. *Accu*Detect® is not a diagnostic device, as the CAD marks are intended to be used to assist only in detection and not in interpretation. Therefore, *Accu*Detect® can assist a radiologist in detecting areas of concern that would have been missed without its use, but if used properly it cannot cause a radiologist to miss areas of concern that would have been detected without *Accu*Detect®.

It is important to remember that *Accu*Detect® will not necessarily mark what a radiologist would work-up. This is an important consideration as every radiologist works-up different areas based on her or his own criteria.
*Accu*Detect® does not function on its own, but always with a radiologist. Therefore, if *Accu*Detect® identifies a soft tissue density or calcifications in one view only, the radiologist can look for it in the other view to determine if there is a lesion that warrants work-up.

5 Parascript® AccuDetect® Device Labeling

5.1 Brief Device Description

Parascript® *Accu*Detect® is a Computer-Aided Detection (CAD) software device intended to aid radiologists reading mammograms. It is a proprietary software application designed to process digital images. The digital mammography images are automatically analyzed to identify areas suspicious for possible soft tissue densities and/or calcifications. Parascript® *Accu*Detect® works in conjunction with a review workstation, which shows suspicious areas identified by the software by means of marks superimposed on the mammogram.

Results are displayed on a computer monitor for review by a radiologist. The radiologist is instructed to first review each case in the conventional manner and then re-examine the case utilizing the information supplied by the Parascript® *Accu*Detect system before making a final assessment for the case.

5.2 Indications for Use

The Parascript® *Accu*Detect® is intended for use in screening mammography to identify areas suspicious for breast cancer for radiologist review after completing an initial read.

5.3 Contraindications

There are no contraindications for this device.

5.4 Warnings

Parascript® *Accu*Detect® is a Computer Aided Detection (CAD) software designed for a computerized second read of mammography images to suggest radiologists that a suspicious area requires further investigation. It is intended to identify suspicious areas, for their better localization. The diagnosis is always performed only by the radiologist after her/his in depth analysis of the mammogram. The system can assist the radiologist by identifying regions that may warrant a more meticulous review.

- Do not use *Accu*Detect® software without proper training. Operator training and review of the user manuals for *Accu*Detect® CAD is required prior to using the System.
- It is critical that the radiologist reviews the mammograms in the conventional manner first, before reviewing the *Accu*Detect CAD results. Reviewing *Accu*Detect system results before reviewing the mammograms could cause the radiologist to fail to examine the unmarked areas with adequate care.
- *Accu*Detect CAD will not mark all regions that are indicative of cancer.
- *Accu*Detect CAD marks many suspicious areas that do not represent cancer, and the user must still use interpretative skills when reviewing the marked items.
- *Accu*Detect CAD results assist only in the detection of suspicious regions of the mammogram. Therefore, the presence of a mark only indicates that a radiologist should review the marked region again to avoid a potential oversight.
- *Accu*Detect CAD may not detect a lesion in both views.
- *Accu*Detect CAD will mark regions that do not contain cancer.
- Mass false positives can occur on benign masses, lymph nodes, blood vessels, superimposing normal tissue, skin folds, and areas of higher density caused by normal parenchymal structures.
- Calcification false positives can occur on vascular calcifications, lucent calcifications, secretory calcifications, and small breast tissue structures.
- Calcification false positives can also occur on artifacts such as those caused by deodorant, powders, or other types of ointments on the skin. Image quantum noise may also cause false positive calcification marks.
- *Accu*Detect CAD is not designed to detect skin thickening or nipple retraction.

- *Accu*Detect CAD will not detect changes from prior mammograms.
- *Accu*Detect CAD is not intended to analyze views containing a breast that is too large to fit on the image.
- *Accu*Detect CAD is not intended for diagnostic purposes. Effectiveness has not been established for diagnostic views (e.g., magnification or compression views). These views should not be analyzed with *Accu*Detect CAD.
- *Accu*Detect CAD is not intended to analyze views that include an implant. Effectiveness has not been established for views that include the implant.
- *Accu*Detect CAD is not intended to analyze implant displaced views. Effectiveness has not been established for implant displaced views.
- *Accu*Detect CAD has not been tested on images having prior breast interventions including prior surgical biopsy and placement of an internal breast marker. Effectiveness has not been established for this population of cases.
- Typical screening mammography includes four mammographic views: left and right craniocaudal projections (L-CC and R-CC) and left and right mediolateral oblique projections (L-MLO and R-MLO). AccuDetect CAD supports cases that do not have all screening views mentioned above. However, the absence of one or more views will affect the performance of the algorithm. Effectiveness has not been established for cases that do not have all screening views.
- *Accu*Detect CAD functions with different projections such as ML and LM views. However, effectiveness has not been established for cases that include any projections which are different from one of the following: L-CC, R-CC, L-MLO, R-MLO.
- Effectiveness and safety have not been established for non-standard mammographic views (e.g., magnification/compression views). When these views are analyzed by the system, any resulting CAD marks should not be used by the radiologist in evaluating the patient.
- *Accu*Detect CAD may not detect all errors in image orientation and DICOM tags (for example image laterality tag, view position tag, etc.) All images must be provided to *Accu*Detect CAD in proper orientation and have the appropriate DICOM tags.

GENERAL WARNINGS FOR OPERATORS OF COMPUTING EQUIPMENT

- *Accu*Detect CAD is intended to be the only device operating on the computing equipment on which it is installed. No other applications are to be installed.
- Operation of electronic equipment requires precautions to prevent electric shock. Never open any covers of any equipment. In the case of objects or liquids that may have gotten into the equipment, please unplug the equipment and contact authorized service personnel.
- Only use grounded power sources for computing equipment. Use only grounded extension cables, and no adapters. Contact authorized service or installation personnel to solve any cabling problems. Keep cables out of the way to avoid damage to the cables. Be sure that nothing rests on the system's cables and that the cables are not located where they can be stepped on or tripped over.

- Most computing equipment relies on proper ventilation. Do not cover any openings, and do not place any objects on computing equipment to avoid thermal problems.
- Certain components of the *Accu*Detect system are standard computing and display equipment that can generate and radiate radio frequency energy. If the components are not used in accordance with the instruction manual, they may cause harmful interference to radio communications. Operation may cause unacceptable interference to radio and TV reception. The system must not be operated in the vicinity of medical devices labeled as having, or known to have, potential interference with standard computers and display monitors.

5.5 Adverse effects

There are no known direct risks to safety or health of the user or the patient that are related to the use of the device. There is no direct contact with the patient.
Indirect inherent risks are: (a) that the device may not mark actionable areas; and (b) that the device may mark regions that are not actionable. These possibilities are clearly explained in the warnings included in the labeling of the device. Proper use of the marks generated by the device is explained in the directions for use of the device.

5.6 Summary of Clinical Studies

5.6.1 Clinical Studies Overview

The primary objective of the clinical studies was to determine whether radiologists are more effective at reading digital mammograms when using the Parascript *Accu*Detect Computer Aided Detection (CAD) software versus when not using CAD software. The purpose of the clinical performance assessment of *Accu*Detect® CAD was to demonstrate the clinical safety and effectiveness of the *Accu*Detect® CAD when used as a second reader in screening mammography.

Intrinsic Imaging, LLC served as the Clinical Research Organization for the reader study under the direction of the Primary Investigator, Dr. Amit Mehta.

The following retrospective studies were performed:

- A pivotal reader study “Comparison of Reader Performance for Screening Mammography Without and With Parascript® *Accu*Detect® Computer Aided Detection” was conducted to compare the effectiveness of radiologists reading screening digital mammograms when using Parascript *Accu*Detect CAD versus when not using CAD.

- The Parascript® *Accu*Detect® CAD standalone study to measure behavior of the *Accu*Detect CAD software.

5.6.2 Reader Study

5.6.2.1 Readers and Cases

The Pivotal Study was conducted with 12 radiologists reading 240 cases. The group of radiologists included general and specialized radiologists. Six general radiologists read less than 3,000 cases per year and six specialized radiologists read more than 3,000 cases per year.

The cases for the study consisted of a randomly selected set of 240 screening FFDM cases acquired on Philips MDM (Microdose Mammography) L30 and GE Senographe Essential FFDM devices (120 cases with cancer,108 normal cases, and 12 cases with actionable benign findings). The GE Senographe Essential data set contained the same number and types of cases as the Philips MDM L30 data set (each set contained 60 cancer cases, 54 normal cases, and 6 actionable benign cases).

The cases were collected from 3 sites in the United States and 2 sites in Europe (one in Belgium and one in Switzerland). All U.S. sites received approval to provide cases for this study by their respective Institutional Review Boards. The European sites were selected due to insufficient supply of retrospective images for Philips MicroDose FFDM in the United States. The European sites followed laws and regulations in their countries and received corresponding approvals for the data collection.

Cases used in the reader study were selected from the pool of accrued cases to conform to a representative sample of screening examinations:

- Positive cases were defined as ones for which there is a mammography visible lesion that was proven by biopsy to represent a cancer.
- Normal cases were defined as ones for which there is a negative index digital mammogram and a subsequent negative mammogram 320-450 days following the index exam (with no cancer diagnosed during this period);
- Recall cases were defined as ones for which further evaluation (e.g., additional mammographic views, breast US, etc.) was recommended during the interpretation of the screening mammograms.
- Actionable benign cases were defined as recall cases for which either subsequent diagnostic investigation or biopsy did not demonstrate cancer.

The inclusion and exclusion criteria for screening mammography cases were as follows:

Inclusion Criteria:

- Female
- Any ethnic origin
- Have a four-view screening digital mammogram
- Have a negative index digital mammogram and a subsequent negative mammogram 320-450 days following the index exam (with no cancer diagnosed during this period); a finding shown by biopsy or follow-up imaging to be a benign abnormality; or, for cases with cancer, a lesion evident on the screening mammogram and a follow-up biopsy demonstrating breast cancer

- Have provided consent (as required by IRB and local laws) for images and protected health information to be used for further research
- Meet none of the exclusion criteria

Exclusion Criteria:

- Subjects having any contraindications to mammographic screening, including but not limited to:
    - Significant existing breast trauma
    - Pregnancy
    - Lactating
- Previous surgical biopsy
- Previous breast cancer
- Placement of an internal breast marker
- Presence of a breast implant
- Presence of a pacemaker
- Inadequate technical quality mammography images, such as insufficient anatomical coverage

Each site submitted de-identified digital mammograms, images (overlays) indicating the location of each known cancer, reference standard-based truth (biopsy for positive cases; follow up mammogram for normal cases and follow-up mammogram or biopsy for actionable benign cases), de-identified clinical reports (including radiology, surgical, and pathology reports), and study-specific case report forms.

5.6.2.2 Reader Study Execution

The clinical reader study was conducted at Intrinsic Imaging, LLC located in 8401 Datapoint, Suite 600, San Antonio, Texas 78229. Intrinsic Imaging is a clinical research organization and a medical imaging core lab providing expert image management and radiological review services to global pharmaceutical, biotechnology and medical device organizations. As a member of the South Texas Radiology Group (STRG) family of companies, Intrinsic Imaging was able to provide conditions of a typical clinical environment, including temperature, ambient light, light sources (less than 50 lux), level of comfort, type of furnishings, and ambient noise. All medical physics evaluations in the mammography room were performed prior to the study according to the prescriptions of state and national agencies.

12 Readers performed sequential readings of 240 cases (120 with malignant lesions, 108 normal cases, and 12 cases with actionable benign findings). The readers read each case unassisted, recorded the results of that reading, then turned on *Accu*Detect CAD as a “second reader”. Once the findings of the unassisted read have been stored, they could not be altered.

For each case, each reader performed the following actions in order:

1. Evaluate the case without CAD assistance.
2. Record the unassisted assessment for the case.
3. Turn on CAD marks and view the *Accu*Detect marks for the case.
4. Record CAD assisted assessment for the case.

The unassisted and CAD assisted assessments included the following information:

- Readers noted their level of confidence that a malignancy is present on each finding using 1-100 probability of malignancy (POM) scale; they also noted the type of each finding (soft tissue density or calcification).
- Readers noted their level of confidence that a malignancy is present on each case.
- Readers assigned a BI-RADS screening score (0, 1, or 2) to each case.

Each case and each finding were classified as true negative, true positive, false negative, or false positive based on a comparison of the reading with the reference standard-based truth.

5.6.2.3 Pivotal Study Statistical Methods

The statistical analysis estimated a smooth patient-based receiver operating characteristic (ROC) curve for each of the 12 study readers in each test condition (without CAD and with CAD) using the probability of malignancy (POM) ratings each reader provided for each case. The major efficacy criterion used in this study was the area under (AUC) the receiver operator characteristic (ROC) curve. The statistical analysis used the method of Dorfman, Berbaum, and Metz[i,ii]. The ROC curves and AUC for each reader were estimated with 2 different models in version 2.32 build 3 of DBM-MRMC software: Wilcoxon-trapezoidal (non-parametric) and PROPROC (parametric). The statistical analysis treated patients and readers as random effects.

The statistical analysis for secondary endpoints compared AUC between CAD assisted and unassisted lesion-based L-ROC curves (or, in another terminology, Figures of Merit for AFROC curves) which were based on the probability of malignancy (POM) ratings each reader provided for each finding. We used JAFROC software, version 4.1 (described at http://www.devchakraborty.com), which is based on the same method of Dorfman, Berbaum, and Metz.

Also, recall-based specificity and recall-based sensitivities for soft tissue densities, calcifications and overall cancers were compared for unassisted and CAD assisted readings. Bootstrapping[iii] and General Estimation Equations (GEE)[iv] methods were used for calculation of 95% confidence intervals. Subgroup analysis looked at results for 11 subgroups stratified by lesion type (soft tissue densities and calcifications), by manufacturer (GE and Philips), by reader experience (radiologists reading more than 3,000 cases per year and radiologists reading less than 3,000 cases per year), by breast density (categories 1-2 and categories 3-4), and by lesion size (<=10mm, between 10mm and 20mm, and >20mm).

5.6.2.4 Pivotal Study Primary Results

The primary goal of the Pivotal Study was to demonstrate that patient-based ROC curves from CAD assisted mammography are superior to patient-based ROC curves from unassisted mammography. The areas under unassisted and CAD assisted ROC curves, which provide an estimate of the probability that a reader rates malignant cases as more suspicious than non-malignant ones, were estimated using two different models: Wilcoxon-trapezoidal (non-parametric) and PROPROC (parametric). In both cases, the average area under the patient-based ROC curves for radiologists using CAD increased with statistical significance (p = 0.0003 and p = 0.0010) comparing to the average area under the patient-based ROC curves for the same radiologists interpreting the same cases without CAD (see Table 1). Figure 2 shows graphs of the unassisted and CAD assisted ROC curves averaged over the parametric reader ROC curves.

Table 1. Primary Results of Pivotal Study: The Increase in Patient-based ROC AUC

model	No CAD (CI)	CAD assisted (CI)	Difference (CI)	P-value
Wilcoxon-Trapezoidal	0.896 (0.862, 0.930)	0.921 (0.893, 0.949)	0.025 (0.013, 0.038)	0.0003
PROPROC	0.914 (0.885, 0.943)	0.930 (0.903, 0.957)	0.016 (0.006, 0.025)	0.0010

Difference = CAD assisted – No CAD
CI = 95% Confidence Interval

The results in the table above demonstrate that the primary goal of the study was met. The use of Parascript® *Accu*Detect® led to a significant increase in effectiveness for the group of 12 radiologists reading digital mammograms.

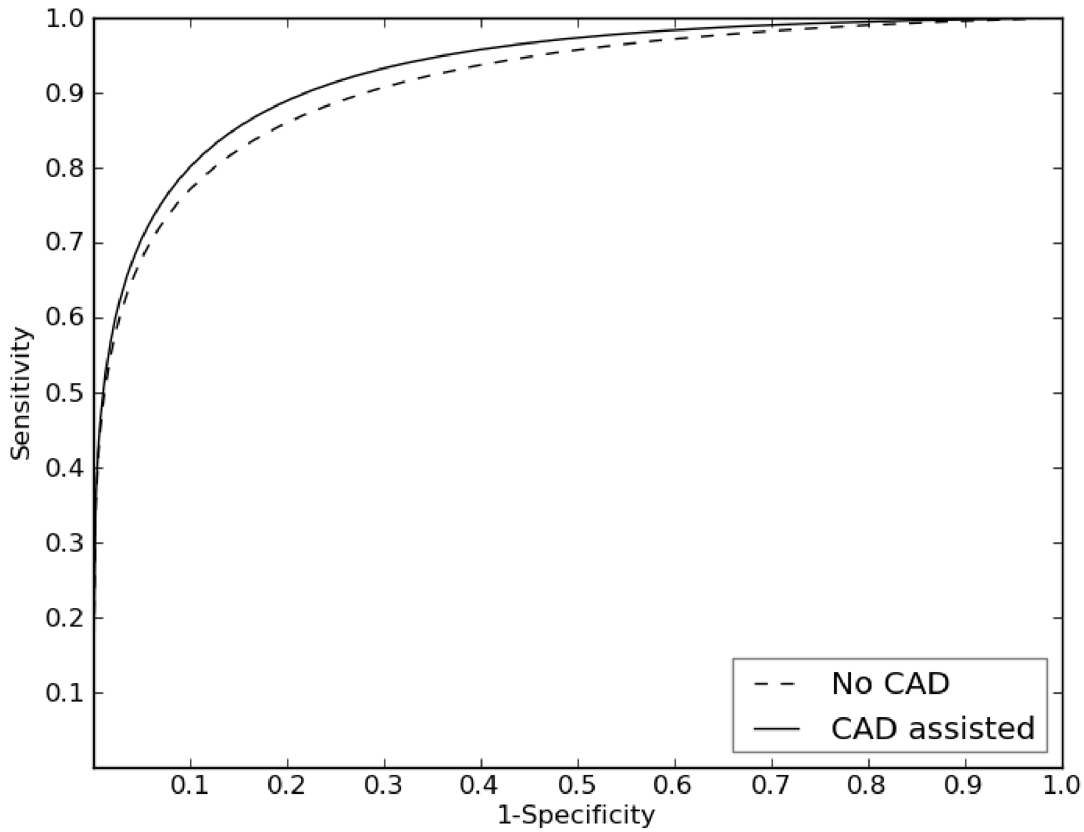


Figure 2. Unassisted and CAD assisted patient-based ROC curves averaged over the readers

5.6.2.5 Pivotal Study Secondary Results

The secondary analysis was performed for informational purposes. The analysis included the area under lesion-based L-ROC curves for overall cancers, for soft tissue densities, and for calcifications; it included the area under patient-based ROC curves for GE images and Philips images as well as for radiologists reading more than 3,000 cases per year and for radiologists reading less than 3,000 cases per year; it also included recall-based sensitivity (for overall cancers, for soft tissue densities, for calcifications, for GE images, for Philips images) and recall-based specificity (overall, GE images and Philips images).

All confidence intervals were calculated without adjustment for multiplicity, thus the statistical significance of the difference of performance with and without CAD cannot be assessed for secondary endpoints.

Figure 3 shows graphs of the unassisted and CAD assisted L-ROC curves averaged over the readers.

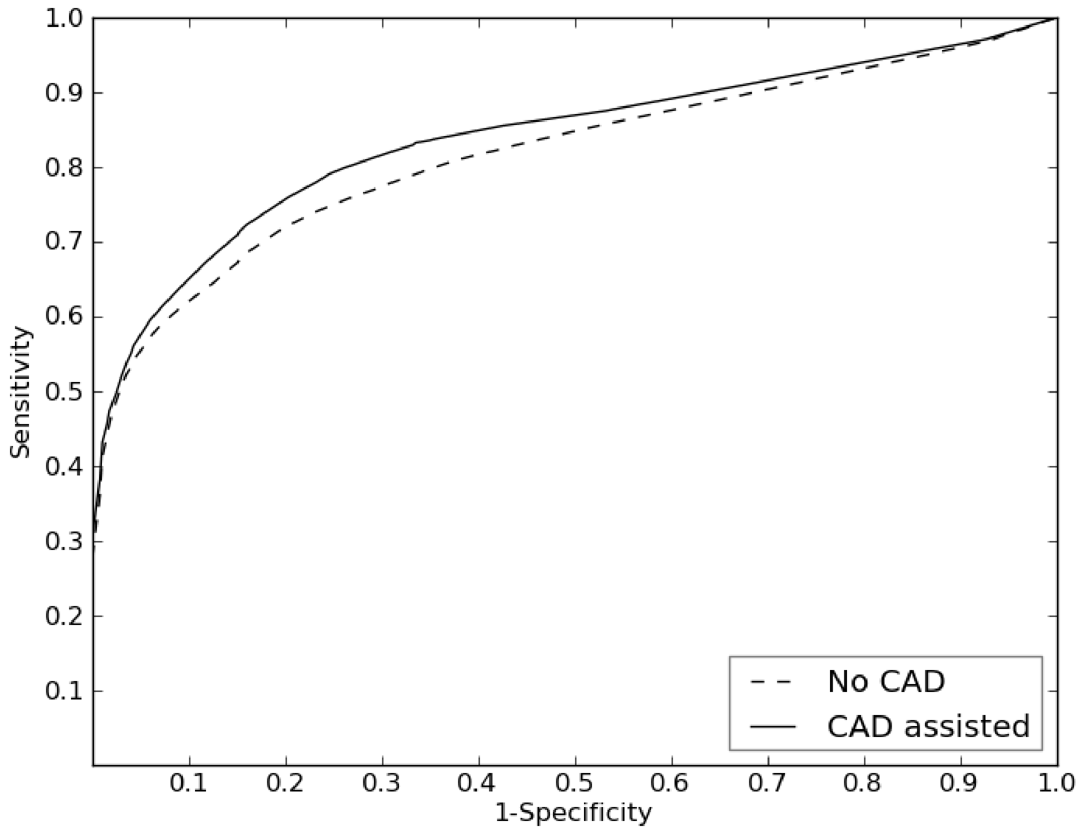


Figure 3. Unassisted and CAD assisted lesion-based L-ROC curves averaged over the readers

The average area under the lesion-based L-ROC curves for radiologists using CAD increased comparing to the average area under the lesion-based L-ROC curves for the same radiologists interpreting the same cases without CAD. The increase was observed for both lesion type subgroups as well as for overall cancers (see Table 2).

Table 2. The Increase in Lesion-based L-ROC AUC

Group	No CAD (CI)	CAD assisted (CI)	Difference (CI)
Overall	0.817 (0.773, 0.861)	0.838 (0.798, 0.879)	0.021 (0.011, 0.031)
Soft Tissue Densities	0.825 (0.776, 0.874)	0.848 (0.803, 0.893)	0.023 (0.012, 0.035)
Calcifications	0.897 (0.858, 0.937)	0.910 (0.873, 0.947)	0.013 (0.003, 0.022)

Difference = CAD assisted – No CAD

CI = 95% Confidence Interval

The average area under the patient-based ROC curves for radiologists using CAD increased comparing to the average area under the patient-based ROC curves for the same radiologists interpreting the same cases without CAD for subgroups stratified by manufacturer (GE and Philips) and by reader experience (radiologists reading more than 3,000 cases per year and radiologists reading less than 3,000 cases per year) (Table 3).

Table 3. The Increase in Patient-based ROC AUC for subgroups

Subgroup	No CAD (CI)	CAD assisted (CI)	Difference (CI)
GE	0.904 (0.858, 0.951)	0.932 (0.896, 0.968)	0.028 (0.009, 0.047)
Philips	0.892 (0.849, 0.934)	0.914 (0.875, 0.952)	0.022 (0.008, 0.037)
Breast Specialists (> 3,000 cases per year)	0.905 (0.873, 0.937)	0.928 (0.902, 0.954)	0.023 (0.007, 0.038)
General Radiologists (< 3,000 cases per year)	0.887 (0.834, 0.940)	0.915 (0.877, 0.952)	0.028 (0.007, 0.049)

The average recall-based sensitivity increased from 0.919 without CAD to 0.934 with CAD (see Table 4). This represents 1.5% more cancers detected and 18.8% of missed cancers detected. Also, sensitivity increased for both lesion type subgroups and for both manufacturer subgroups.

Table 4. The Increase in Recall-based Sensitivity

Group	No CAD (CI)	CAD assisted (CI)	Difference (CI)
Overall	0.919 (0.878, 0.946)	0.934 (0.892, 0.960)	0.015 (0.003, 0.029)
Soft Tissue Densities	0.854 (0.785, 0.901)	0.882 (0.814, 0.927)	0.027 (0.011, 0.047)
Calcifications	0.933 (0.864, 0.962)	0.939 (0.870, 0.969)	0.006 (-0.009, 0.016)
GE	0.931 (0.884, 0.961)	0.949 (0.885, 0.978)	0.018 (0.003, 0.036)
Philips	0.907 (0.839, 0.946)	0.919 (0.851, 0.958)	0.0125 (-0.006, 0.037)

Difference = CAD assisted – No CAD
CI = 95% Confidence Interval

The average recall-based specificity increased from 0.655 without CAD to 0.703 with CAD (see Table 5). This represents 4.9% less normal cases recalled. Recall-based specificity also increased for both manufacturer subgroups.

Table 5. The Increase in Recall-based Specificity

Group	No CAD (CI)	CAD assisted (CI)	Difference (CI)
Overall	0.655 (0.602, 0.705)	0.703 (0.647, 0.753)	0.049 (0.029, 0.067)
GE	0.636 (0.558, 0.707)	0.692 (0.608, 0.765)	0.056 (0.028, 0.082)
Philips	0.674 (0.603, 0.739)	0.715 (0.638, 0.779)	0.042 (0.017, 0.067)

Difference = CAD assisted – No CAD
CI = 95% Confidence Interval

5.6.3 CAD Standalone Study

Sensitivity, specificity and false positive rate of CAD (overall and for different subgroups) were measured in the CAD Standalone Study. The data set consisted of 300 cases (150 with malignant lesions, 135 normal cases, and 15 cases with actionable benign findings). There were 140 GE cases and 160 Philips cases in the set. 10% of non-cancer cases were actionable benign cases for each FFDM system.

Sensitivity was measured as a number of positive cases where at least one true positive mark is present divided by the total number of positive cases; specificity was measured as a number of normal and actionable benign cases without marks divided by the total number of normal and actionable benign cases; false positive rate (per image) was measured as a total number of marks in normal and actionable benign cases divided by the total number of images in normal and actionable benign cases.

Table 6 shows CAD sensitivity, specificity and false positive rate on the 150 cancer and 150 normal cases used in the Standalone Study as well as separately for calcifications and soft tissue densities. Table 7 shows CAD sensitivity by cancer lesion size. Table 8 and

Table 9 show sensitivity and specificity for different breast density categories.

Table 6. CAD Sensitivity, Specificity and False Positive Rate (per Image) with Confidence Intervals

	Sensitivity (CI)	Specificity (CI)	False Positive Rate (CI)
Overall	131/150 = 87.3% (82.0%, 92.7%)	67/150 = 44.7% (36.7%, 52.6%)	256/600 = 0.427 (0.346, 0.508)
Soft tissue densities	90/108 = 83.3% (76.3%, 90.4%)	83/150 = 55.3% (47.4%, 63.3%)	143/600 = 0.238 (0.195, 0.281)
Calcifications	54/60 = 90.0% (82.4%, 97.6%)	110/150 = 73.3% (66.3%, 80.4%)	113/600 = 0.188 (0.141, 0.235)

Table 7. CAD Sensitivity with Confidence Intervals by Lesion Size

Lesion Size (mm)	Overall (CI)	Soft tissue densities (CI)	Calcifications (CI)
<= 10mm	28/36 = 77.8% (64.2%, 91.4%)	18/27 = 66.7% (48.9%, 84.4%)	12/12 ~ 87.9% *) (71.8%, 100%)
>10 and <= 20mm	49/55 = 89.1% (80.9%, 97.3%)	41/47 = 87.2% (77.7%, 96.8%)	14/17 = 82.4% (64.2%, 100.0%)
> 20mm	31/34 = 91.2% (81.6%, 100.0%)	21/23 = 91.3% (79.8%, 100.0%)	15/17 = 88.2% (72.9%, 100.0%)
Unknown	23/25 = 92.0% (81.4%, 100.0%)	10/11 = 90.9% (73.9%, 100.0%)	13/14 = 92.9% (79.4%, 100.0%)

*) In this case the standard method of calculation gives 100% frequency and zero length confidence interval. To obtain more realistic estimate, we use for this cell Agresti-Coull approximate binomial confidence interval (also known as adjusted Wald interval); the frequency is calculated as the midpoint of this interval[v].

Table 8. CAD Sensitivity with Confidence Intervals for by Breast Density

Breast Density	Overall (CI)	Soft tissue densities (CI)	Calcifications (CI)
Fatty	3/3 = 100.0% (N/A)	2/2 = 100.0% (N/A)	1/1 = 100.0% (N/A)
Scattered Fibroglandular	66/74 = 89.2% (82.1%, 96.3%)	45/53 = 84.9% (75.3%, 94.5%)	29/31 = 93.5% (84.9%, 100.0%)
Heterogeneously Dense	53/61 = 86.9% (78.4%, 95.4%)	35/42 = 83.3% (72.1%, 94.6%)	23/25 = 92.0% (81.4%, 100.0%)
Extremely Dense	7/10 = 70.0% (41.6%, 98.4%)	6/9 = 66.7% (35.9%, 97.5%)	1/3 = 33.3% (0.0%, 86.7%)

Table 9. CAD Specificity with Confidence Intervals by Breast Density

Breast Density	Overall (CI)	Soft tissue densities (CI)	Calcifications (CI)
Fatty	9/13 = 69.2% (44.1%, 94.3%)	9/13 = 69.2% (44.1%, 94.3%)	12/13 = 92.3% (77.8%, 100.0%)
Scattered Fibroglandular	28/67 = 41.8% (30.0%, 53.6%)	36/67 = 53.7% (41.8%, 65.7%)	47/67 = 70.1% (59.2%, 81.1%)
Heterogeneously Dense	28/65 = 43.1% (31.0%, 55.1%)	35/65 = 53.8% (41.7%, 66.0%)	48/65 = 73.8% (63.2%, 84.5%)
Extremely Dense	2/5 = 40.0% (0.0%, 82.9%)	3/5 = 60.0% (17.1%, 100.0%)	3/5 = 60.0% (17.1%, 100.0%)

Table 10. CAD False Positive Rate (per Image) with Confidence Intervals by Breast Density

Breast Density	Overall (CI)	Soft tissue densities (CI)	Calcifications (CI)
Fatty	13/52 = 0.250 (0.004, 0.496)	7/52 = 0.135 (0.014, 0.255)	6/52 = 0.115 (0.000, 0.254)
Scattered Fibroglandular	138/268 = 0.515 (0.383, 0.647)	79/268 = 0.295 (0.223, 0.366)	59/268 = 0.220 (0.145, 0.296)
Heterogeneously Dense	97/260 = 0.373 (0.258, 0.488)	54/260 = 0.208 (0.148, 0.268)	43/260 = 0.165 (0.098, 0.233)
Extremely Dense	8/20 = 0.400 (0.040, 0.760)	3/20 = 0.150 (0.000, 0.311)	5/20 = 0.250 (0.000, 0.530)

5.6.4 Conclusions Drawn from Studies

Use of the Parascript® *Accu*Detect® led to an increase in effectiveness of a group of 12 radiologists reading digital mammograms. The results of the pivotal study demonstrate that the performance of the radiologists in discriminating between malignant and nonmalignant cases has been improved with the use of the Parascript® *Accu*Detect® CAD: the average area under ROC curve has increased with statistical significance. In our study, both the reader sensitivity and the reader specificity increased when using the CAD algorithm. However, the confidence intervals have not been adjusted for multiple testing, therefore the statistical significance of the increase in sensitivity and specificity cannot be established.

5.6.5 GE Senographe and Philips MicroDose Image Processing Conclusions

While *Accu*Detect CAD software processed digital images created by GE Senographe Essential and Philips MicroDose FFDMs during the study, AccuDetect CAD can also process GE Senographe images from GE Senographe Care and GE Senographe DS.

GE Senographe Essential and GE Senographe Care are basically the same FFDM units. The only difference is that GE Senographe Care is not upgradable to advanced applications such as Contrast Enhanced Spectral Mammography (CESM) and tomosynthesis. There is no difference between the detectors used in GE Senographe Essential and GE Senographe Care that could impact the performance of *Accu*Detect software.

GE Senographe Essential and GE Senographe DS are the units with the same pixel size (100 µm) but a different field of view: a conventional size 23×19.2cm for DS and a large field 24×30.7cm for Essential, specifically designed to image large breasts. There are no major differences between detectors used in Senographe Essential and Senographe DS that could impact the performance of *Accu*Detect CAD software.

5.7 Principles of Operation

Designed to help radiologists in the detection of breast lesions during mammography exams, *Accu*Detect® automatically identifies areas suspicious for possible soft tissue densities and/or calcifications, enabling a more accurate interpretation of mammograms and increased detection of suspicious breast lesions. To accomplish this task, *Accu*Detect® employs several image recognition processes and sophisticated voting methods within a single CAD system.

Voting approach during image processing and analysis can be likened to the work of a group of highly-skilled experts. When the image recognition processes (also called "recognizers") work together, they complement each other, resulting in improved overall performance. Sophisticated logic analyzes and combines the interim results obtained from the individual recognizers to determine the final result and the corresponding confidence value.

Comparing the results of multiple image recognition processes allows for the mitigation of the inherent faults of a single image recognition process, leading to reduced false-positive and false-negative rates. The fact that *Accu*Detect® uses multiple image recognition processes makes it easy to fully utilize multiple processor systems. They allow image recognition processes to be run in parallel, increasing computational efficiency and spreading the workload across multiple processors. This approach leads to fast processing and accurate results.

Each individual recognizer uses output of preprocessing module, detects suspicious lesions utilizing a variety of image processing and pattern recognition techniques, and sends its hypotheses of lesions to the voter. The voter integrates results of all recognizers using sophisticated voting methods (patent pending) to achieve high sensitivity and low false-positive rates.

The potential lesions detected by *AccuDetect*® CAD consist of suspect soft tissue densities with size between 5mm and 50mm. The potential clusters of calcifications detected by the CAD consist of several calcifications with size between 0.1mm and 0.8mm within 2 cm^2 area.

Parascript® *Accu*Detect is not manufacturer dependent. Image–specific characteristics for each manufacturer are included in the configuration file and used at image preprocessing step only. *Accu*Detect is working at a fixed operating point that can not be changed by the user.

5.8 Conformance to Standards

Parascript® *Accu*Detect® software is installed on standard computing hardware which meets the requirements of the UL standard for Information Technology Equipment per UL1950 or UL60950 as well as the requirements of FCC Part 15 Class A. Computer also complies with the EU Low Voltage Directive as demonstrated by testing to the CENELEC standard EN60950.

The software package was developed in conformance to ANSI/AAMI SW68 Medical Device Software Lifecycle Processes.

5.9 How supplied

Parascript® *Accu*Detect® software is installed by authorized personnel on off-the-shelf standard computing equipment (minimum configuration: Microsoft Windows 7 Professional 64 bits, 2 GHz processor supporting SSE2 instruction set, 4 cores, RAM - 1 GB per core, 100 GB free space on hard drive.

5.10 Installation Instructions

5.10.1 Hardware Preparation

Hardware and operation system should meet requirements specified in item 5.9.

In the event of a power outage, it's important that computer automatically restarts as soon as the power supply is resumed, to minimize downtime. Depending on the computer there are different methods provided for enabling computer restart after a power outage. Thus, Dell servers have a special "AC Power Recovery" option in the BIOS, which allows you to specify how the server behaves in the event of a power outage. For example, if you work on the Dell Precision T3500 workstation you should execute the following steps:

- Power on the Dell server, and press the "F2" key on the server's keyboard when you see the message "<F2> = System Setup" to enter the server's BIOS settings. If you miss this and the server starts loading the operating system, let the system finish loading and then restart the server and try again.

- Use the "Down Arrow" key to move to the "System Security" menu option and press the "Enter" key to select it. This will display a new page of settings.

- Move down to the "AC Power Recovery" option. This has three options: "On," "Off" and "Last." Set the option to "On," which means that after a power outage, as soon as the supply is resumed, the server will automatically turn on. The "Off" setting tells the server to remain off after the supply is resumed, and "Last" returns the server to the state it was in when the power outage occurred.

- Press the "Esc" key to exit the BIOS, and then select the option "Save Changes and Exit" to store the new settings. The server will then restart, and in the event of a power outage, will automatically restart when the power supply is resumed.

Here is another example: HP Z800:

- Restart HP DL server and wait for prompt for pressing F10 key.
- Press F10 key to enter Hewlett-Packard BIOS Setup Utility.
- Select item **Advanced** from the menu on the screen.
- Select **Power-On Options** from the drop-down menu.
- Select **After Power Loss** option from the list of options.
- Set **PreviousState** as a default to enable automatic restart of the computer after power loss.

5.10.2 Python Installation procedure

1) Install Python 2.7.2 (python-2.7.msi) on your computer before you start installing AccuDetect. The installation of Python is included on installation DVD in the "1 Python" folder. To install it, double click python-2.7.msi and follow the instructions on the screen.
2) Install Python Extensions for Windows (pywin32-214.win32-py2.7.exe). To install it, run pywin32-214.win32-py2.7.exe and follow the instructions on the screen.

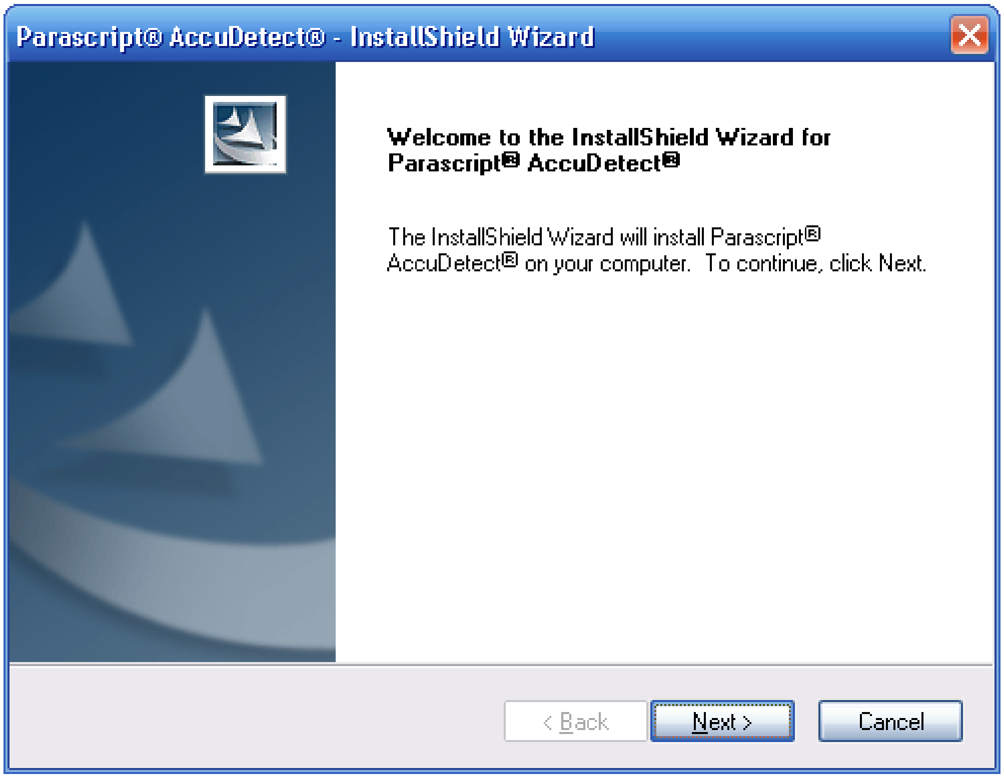
5.10.3 *Accu*Detect CAD Installation procedure

This section describes installation instructions for *Accu*Detect CAD.

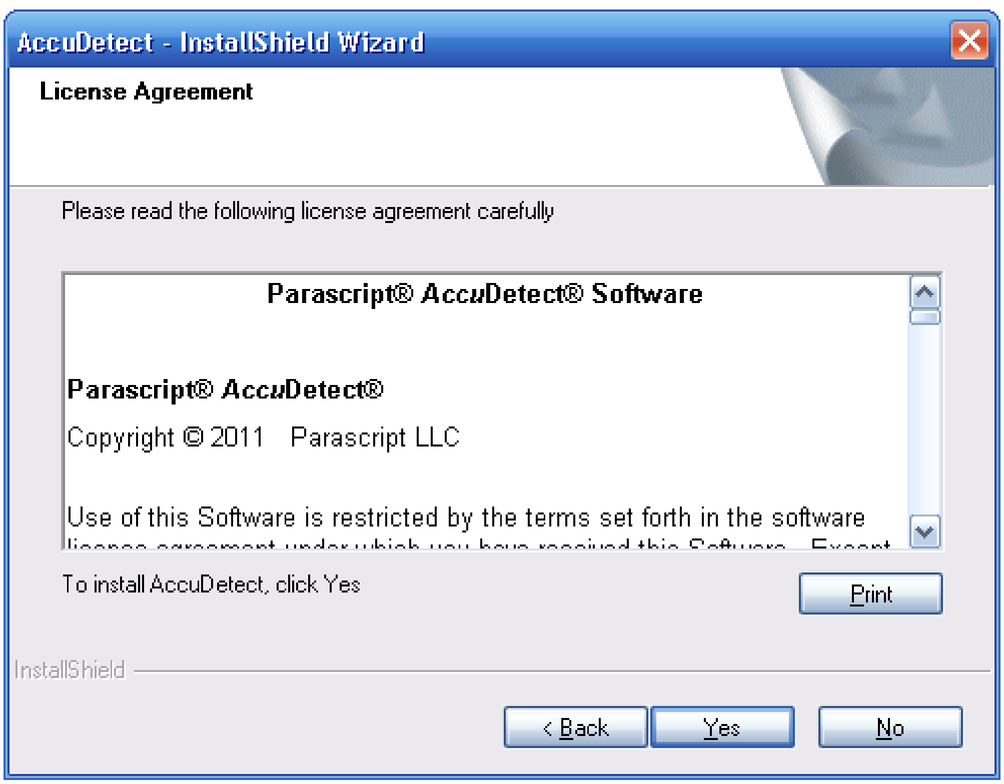
- If you have the *Accu*Detect USB hardlock, insert it to computer before you start the installation.
- Turn off Windows firewall using the standard Window procedures.
- Turn off “computer hibernation”, turn off “put the computer to sleep”, turn off “turn off hard disk”, turn off “allow the computer to turn off network card” using the standard Window procedures.

<u>To install AccuDetect CAD:</u>

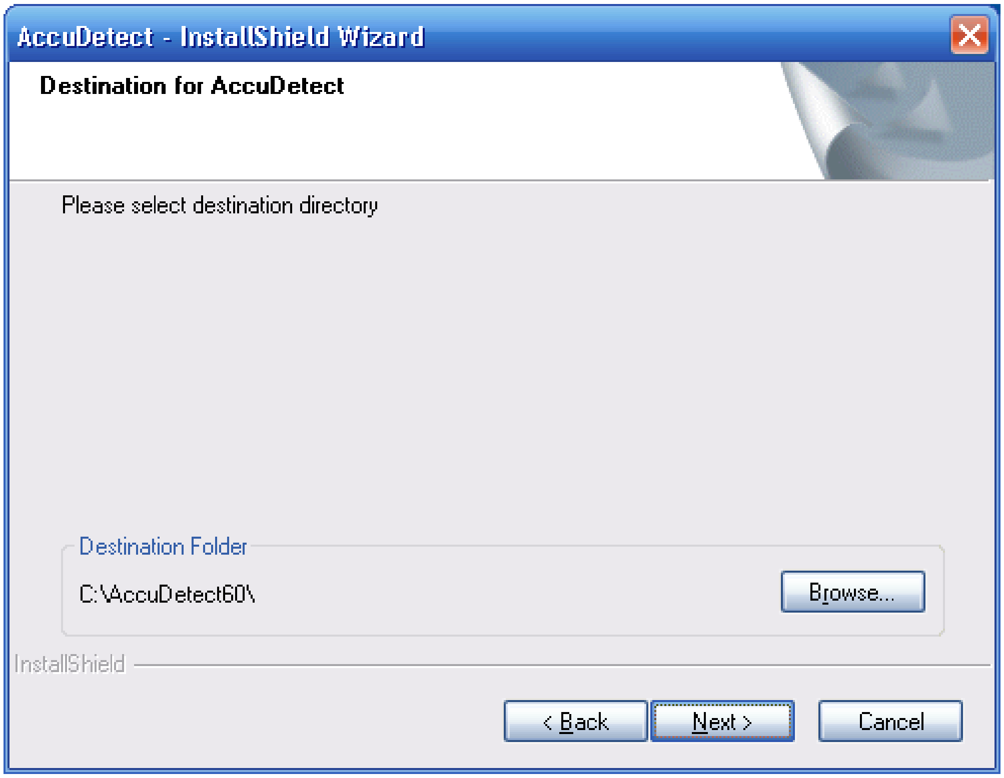
1. Run Setup.exe file from "2 AccuDetect" on installation DVD. The Welcome window appears.



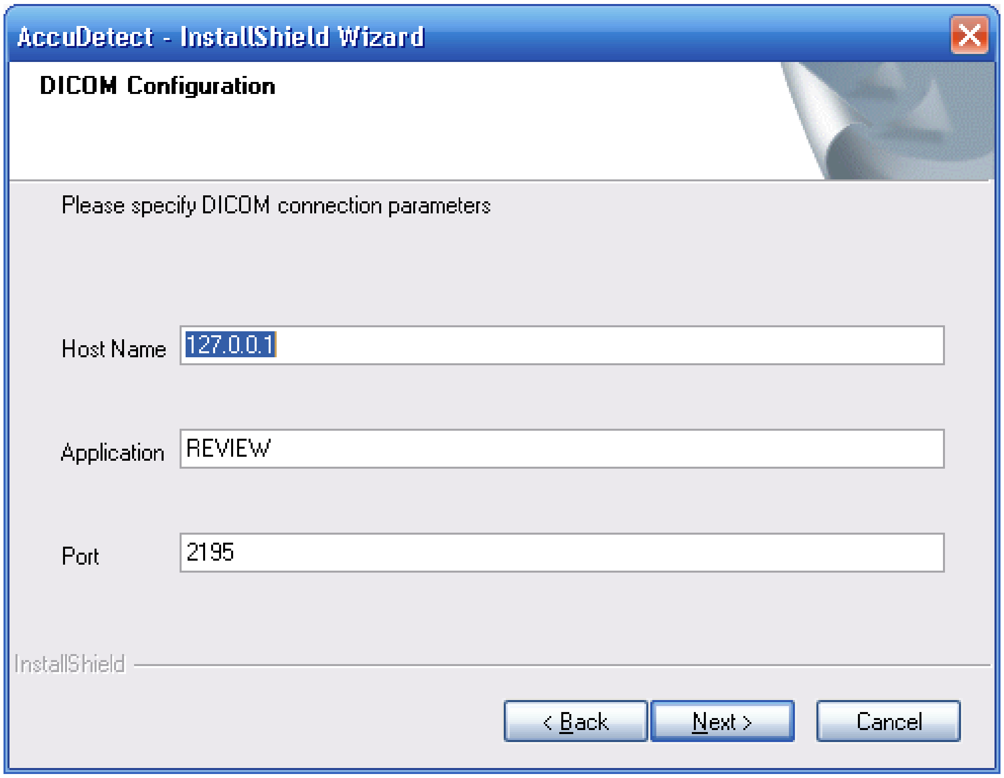
2. Click **Next**. The Restricted Rights Notice window displays.



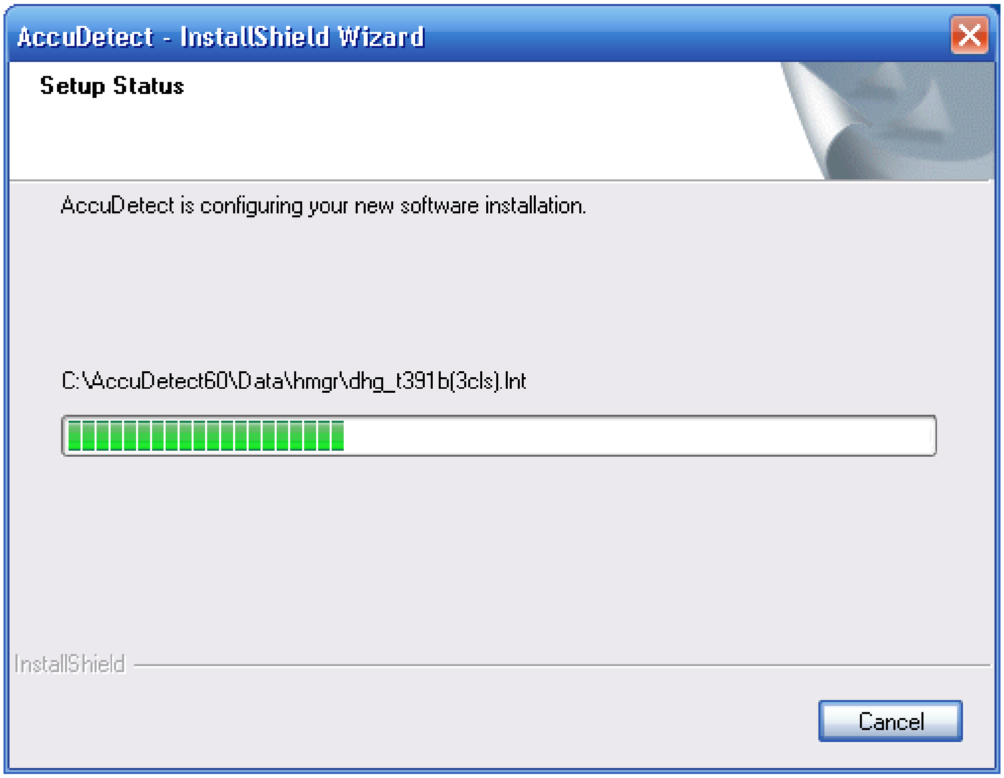
3. If you agree with Restricted Rights Notice, click **Yes**. In the Destination Location window select folder where Setup will install files and press **Next**.



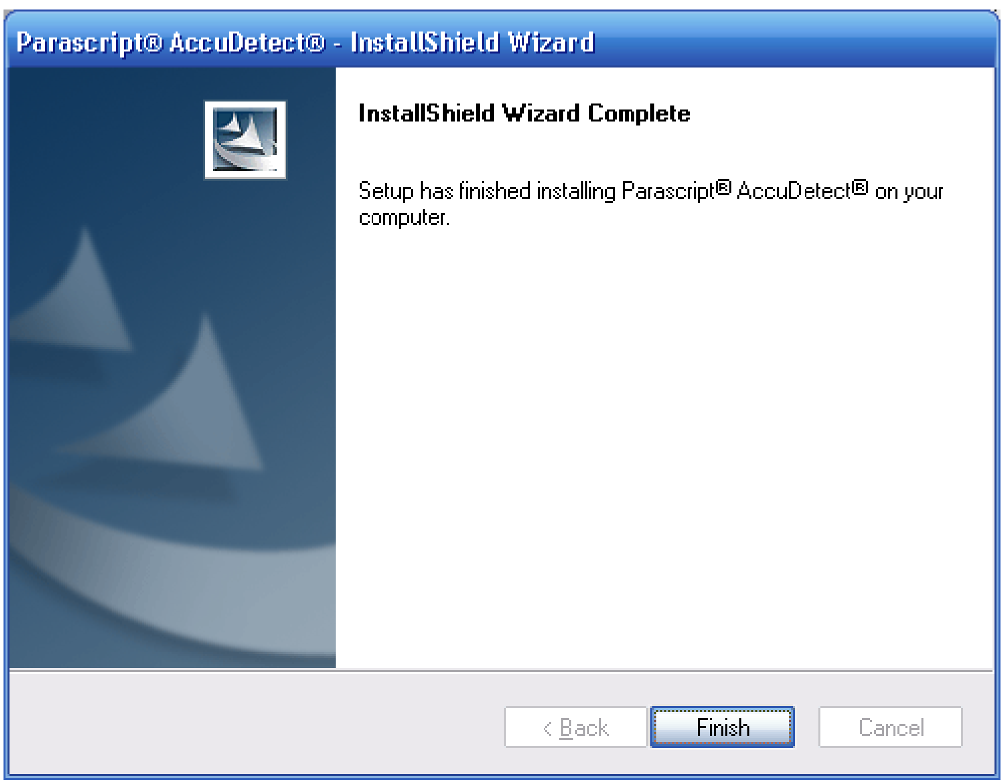
4. Select a folder for *Accu*Detect installation. Please make sure that you have at least 100GB of free disk space on the disk which you choose for the installation. The DICOM Configuration window appears.



5. In the DICOM Configuration window specify DICOM connection parameters that AccuDetect will use to upload structured reports to the output device (i.e. review workstation). You can also specify it later through *Accu*Detect Web configuration utility. With this utility you can also perform a more thorough configuration of a **Sender** and add additional **Senders** if necessary. Setup Status window will be displayed on the screen.



6. When finished, the system displays the **Complete** window presented below. Click **Finish**.



5.11 How to include AccuDetect CAD in hospital environment

1. AccuDetect CAD Login information
   User Name/Password – administrator/para123

2. Connect CAD computer to the network

   - Plug network cable into your CAD computer NIC

   - Execute all actions necessary in your network environment to activate the connection

3. Use standard Microsoft® Windows 7 procedures to set IP address for CAD computer

   - Assign a fixed IP4 address to CAD computer. Set all necessary TCP/IP settings on CAD computer (DNS and WINS).

   - Include CAD computer in your domain or workgroup if required by the policy.

4. Identify all input devices for CAD. This may include FFDM device(s), PACS, Review Workstation(s). For each device collect the following information:

   a. IP address

5. Identify all output devices for CAD. This may include PACS, Review Workstation(s). For each device collect the following information:

   a. IP address

   b. TCP/IP Port

   c. DICOM Application Entity Title

6. If there are firewalls in the network environment that may prevent communication between CAD computer and input and output devices, make changes to the firewalls to enable this communication.

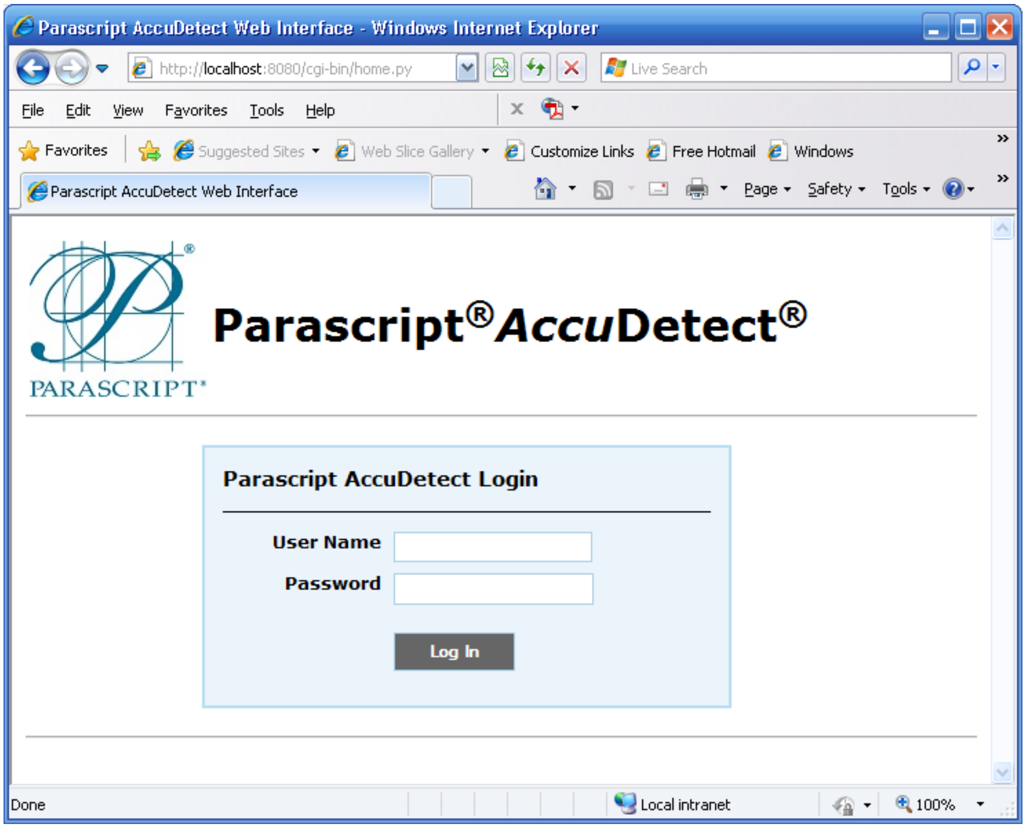
7. Ping from CAD to all input and output devices to ensure that there is a TCP/IP connection between CAD and all input and output devices.

8. Ping from all input and output devices to CAD to ensure that there is a TCP/IP connection between CAD and all input and output devices.

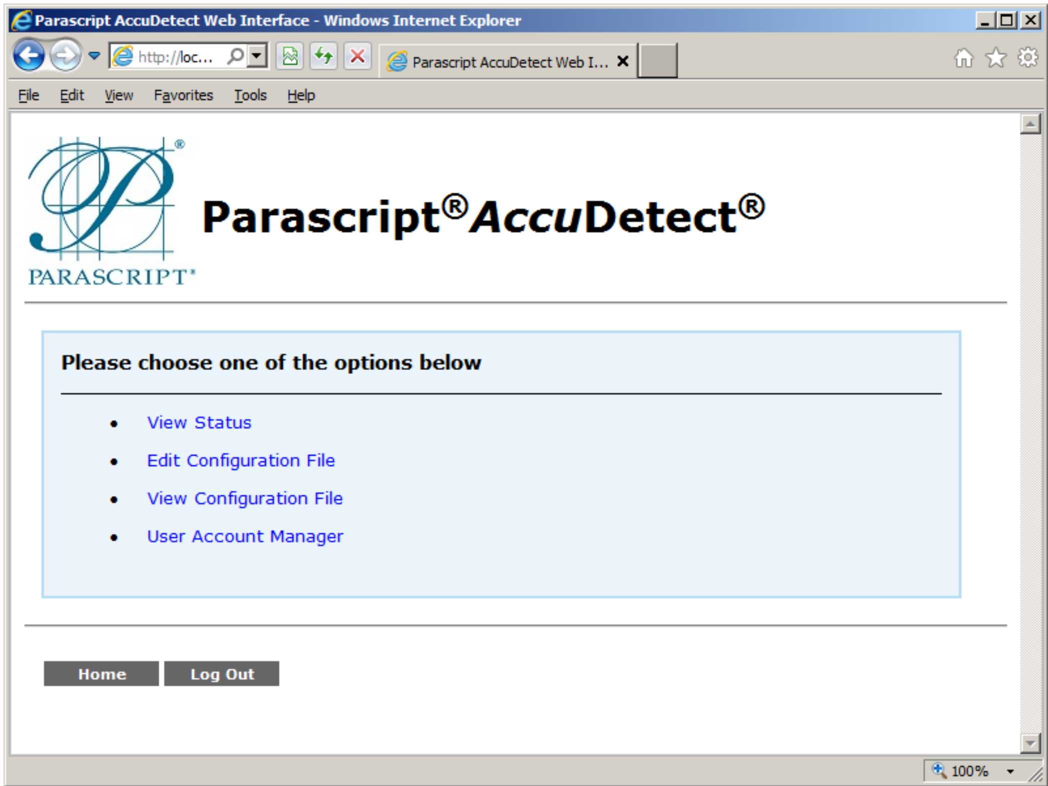
9. For each input device create AccuDetect's Listener Module. To do this:

   a) Run Internet Explorer or any other Web Browser. Type the following address in the address bar: http://address_of_CAD_computer:8080.
   Address_of_CAD_computer should be the name or IP address of the computer,

where CAD is installed. Examples of addresses: http://localhost:8080 - if you run utility on the same computer or http://192.168.20.173:8080 – if you run utility from other computer and CAD computer has IP address 192.168.20.173.
Parascript AccuDetect login screen will be displayed. Enter the username and password to login. AccuDetect's Web Configuration Utility has a built-in user administrator with a password para123. This password could be changed later.



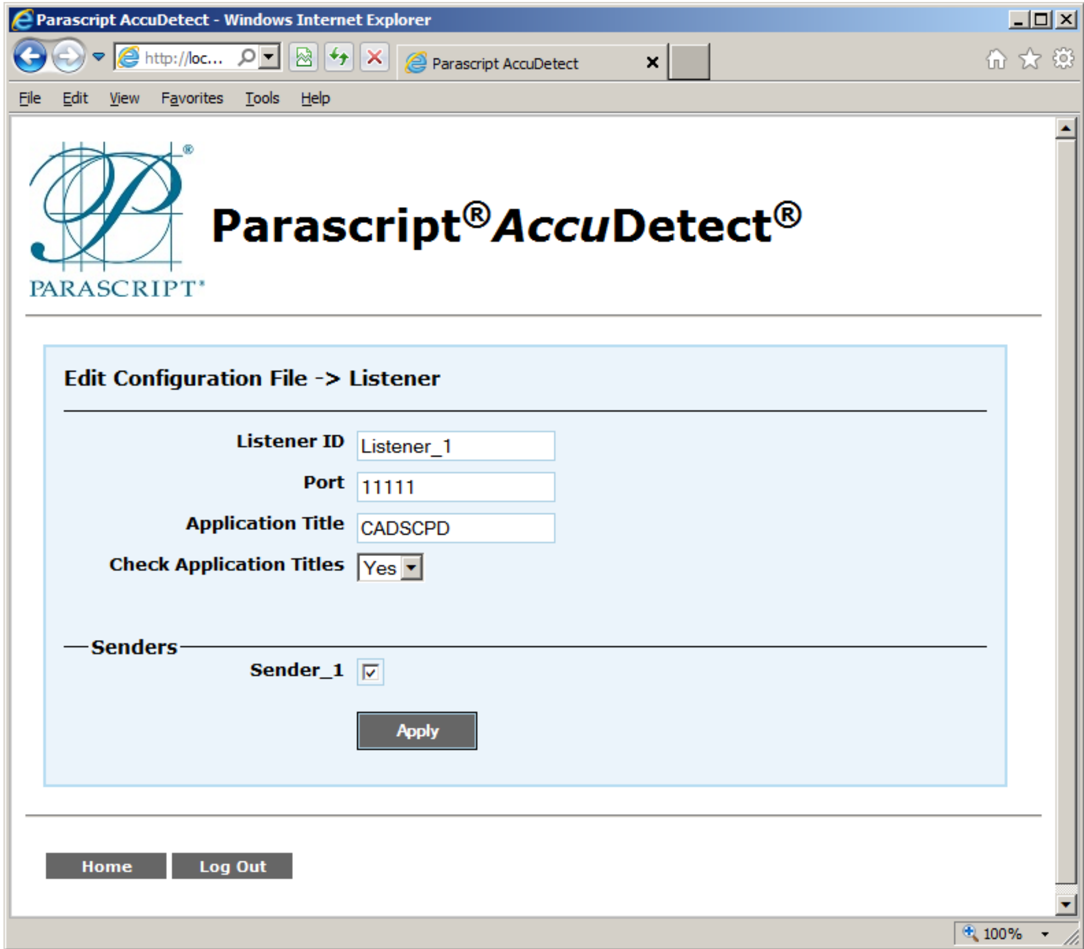
b) Click Log In. Parascript AccuDetect home screen will be displayed in the main window:



c) Click **Edit Configuration File** to edit the configuration file. A window that allows access to all sections of the Configuration file is displayed on the screen.

d) Section **Listeners** allows organizing the process of receiving DICOM images from one or more sources. Here you can add new **Listener** module, edit or delete an existing one.

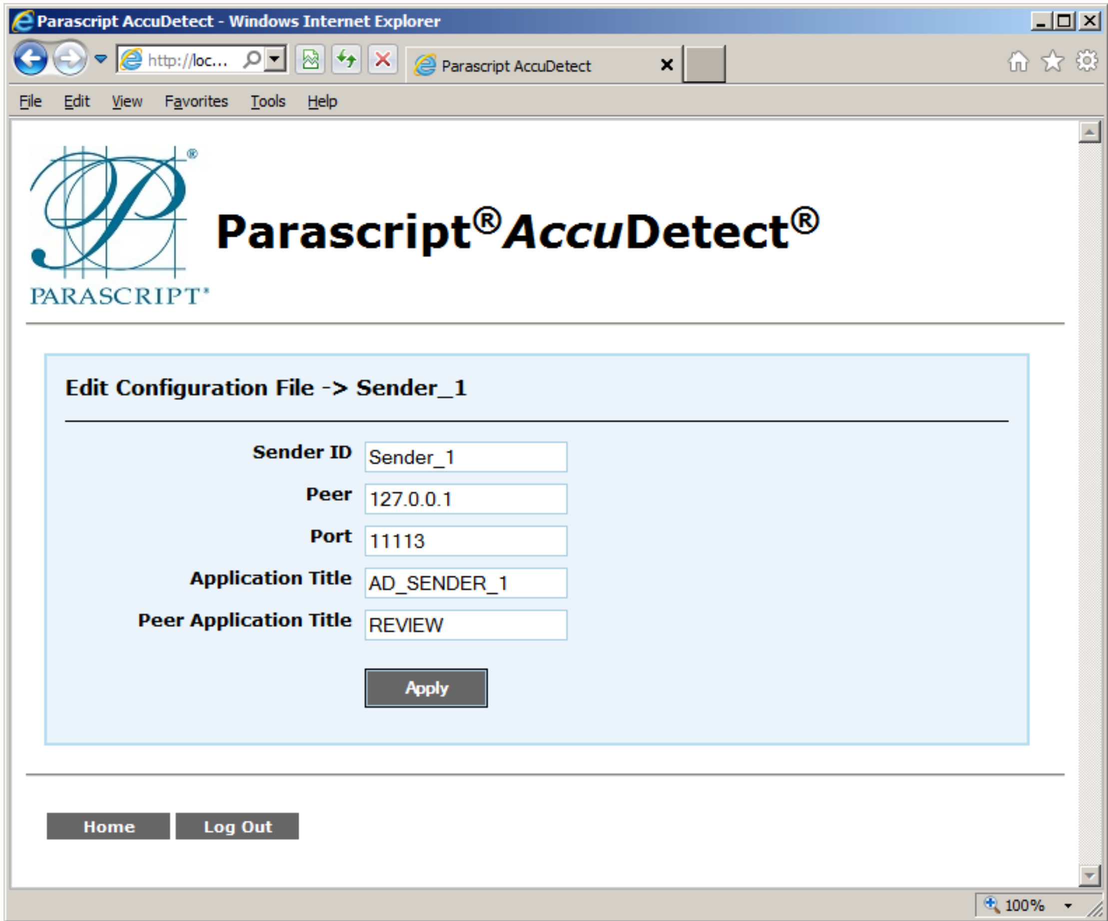
e) Click **Edit** near Listener_1 menu item to edit the Listener parameters. The following window will be shown on the screen:



Parameters that may be edited are as follows:
- Listener ID – Each **Listener** has a unique ID that can be specified or changed.
- Port –TCP/IP port for DICOM connection.
- Application Title – DICOM's Application Entity Title of AccuDetect CAD.
- Check Application Titles – check if sending application defines correct title of the **Listener** (Yes/No) If Check ApplicationTitles parameter is set to Yes, then the **Listener** does not accept DICOM connection requests specifying different Application Title.

10. For each output device create AccuDetect's Sender module and configure it using data collected in step 5. To do this:

    a) Click **Enter** near sender_1 menu item to edit the sender parameters in the **Edit Configuration File** window. The following window will be displayed on the screen:



Parameters that may be edited are as follows:
- Sender ID – Each **Sender** has a unique ID that can be specified or changed.
- Peer – IP address or computer name, where Structured Report will be sent.
- Port – Parameter that specifies TCP/IP Port of the computer where Structured Report will be sent.
- Application Title – AccuDetect's Application Entity Title.
- Peer Application Title – Application Entity Title of the receiving modality.

11. Configure all necessary settings for the input and output devices that will enable them to send for Processing Images to the CAD and receive Structured Reports from the CAD device.

12. Send DICOM echo/verification message from each input device to CAD as defined in the instructions for your input devices.

13. Send test cases from each input device and check if results come to each output device. Refer to the instructions to your input devices for the information on how to send a case to CAD. Refer to the instructions to your output devices to check what has been received from CAD.

5.12 AccuDetect Troubleshooting

A monitor, keyboard and mouse are required to access CAD computer for troubleshooting purposes.

Problem	Cause and Solution
Input device cannot send images.	• Check that computer is on. If computer is off turn it on. • Check that input device is configured to send Mammography images to CAD for processing. Configure all necessary settings for the input device that will enable them to send mammography images for processing to the CAD. • Check configuration match between input device and CAD. Verify that IP Address, Port and Application Title on input device and CAD match. If there is a mismatch either ✓ follow the input device instructions to fix this mismatch on the input device or ✓ fix these parameters in AccuDetect CAD (see items 3 and 9e in section 5.11 in the current document). • Check if firewall is enabled on a CAD computer. If firewall is enabled, follow standard Windows 7 procedures to disable the firewall. • Check connection between input device and CAD computer. Ping from CAD to the input device and from the input device to CAD. If ping failed, contact system network administrator to fix the problem. • Send DICOM echo/verification message from the input device to CAD as defined in the instructions for your input device to check that DICOM communication is functioning. If echo failed contact system network administrator to fix the problem. • Check that *Accu*Detect USB hardlock is inserted in the computer. Insert it if it is missing. • Check that *Accu*Detect USB hardlock has not expired. ✓ Start Internet browser. ✓ Type http://127.0.0.1:1947 address in the address line. ✓ Select menu item Sentinel Keys in the menu column on the left side of the screen. A table with a list of hardlocks will be displayed on the screen. ✓ Find line that has word “Local“ in the Location column in the table and press **Feature** button in column Actions of the table. Hardlock features will be displayed on the screen. ✓ Locate the line that has number “103” in the Feature column. Check column Restrictions to verify that Hardlock has not expired (If Hardlock has expired you will see word “Expired” in this column). • Contact Parascript Customer Service if problems persist.
Output device does not receive	• Check that computer is on. If computer is off turn it on.

Structured Reports	• Check that output device is configured to receive Mammography CAD Structured Reports from AccuDetect. Configure all necessary settings for the output device that will enable them to receive Mammography CAD Structured Reports from AccuDetect. • Check configuration match between output device and CAD. Verify that IP Address, Port and Peer Application Title on output device and CAD match. If there is a mismatch either ✓ follow the output device instructions to fix this mismatch on the output device or ✓ fix these parameters in AccuDetect CAD (see item 10 in section 5.11 in the current document). • Check connection between output device and CAD computer. Ping from CAD to the output device and from the output device to CAD. If ping failed, contact system network administrator to fix the problem. • Check that *Accu*Detect USB hardlock is inserted in the computer. Insert it if it is missing. • Check that *Accu*Detect USB hardlock has not expired. ✓ Start Internet browser. ✓ Type http://127.0.0.1:1947 address in the address line. ✓ Select menu item Sentinel Keys in the menu column on the left side of the screen. A table with a list of hardlocks will be displayed on the screen. ✓ Find line that has word “Local“ in the Location column in the table and press **Feature** button in column Actions of the table. Hardlock features will be displayed on the screen. ✓ Locate the line that has number “103” in the Feature column. Check column Restrictions to verify that Hardlock has not expired (If Hardlock has expired you will see word “Expired” in this column). • Contact Parascript Customer Service if problems persist.
Web interface does not work from other than CAD computer	• Ping from the computer where problem occurred to Port 8080 on CAD computer (for example: Ping 192.168.20.120:8080). If ping failed, contact system network administrator to fix the problem. • Contact Parascript Customer Service if problems persist. Contact information is provided in the current document in Section 7 “How to Contact Us”.
Other problem	• Contact Parascript Customer Service if problems persist.

Important! In case of inquiry to Parascript please provide configuration file and log files. Configuration file (config-accudetect.xml) is located in the folder on your computer where AccuDetect is installed. By default it is folder C:\AccuDetect61. Log files are located in the subfolder _workflow\logs in the in the folder on your computer where AccuDetect is installed. All files from this subfolder are required for diagnostics.

6 Using *Accu*Detect® CAD

*Accu*Detect® CAD software is trained by the manufacturer.

During the software training, large quantities of mammography images with soft tissue densities and calcifications as well as normal images are presented to *Accu*Detect CAD in order to train algorithms to recognize suspect areas. As a result, *Accu*Detect software is already trained when delivered to the clients and there is no need to perform any additional training during the software installation process.

The images below illustrate training examples (see Figure 4).

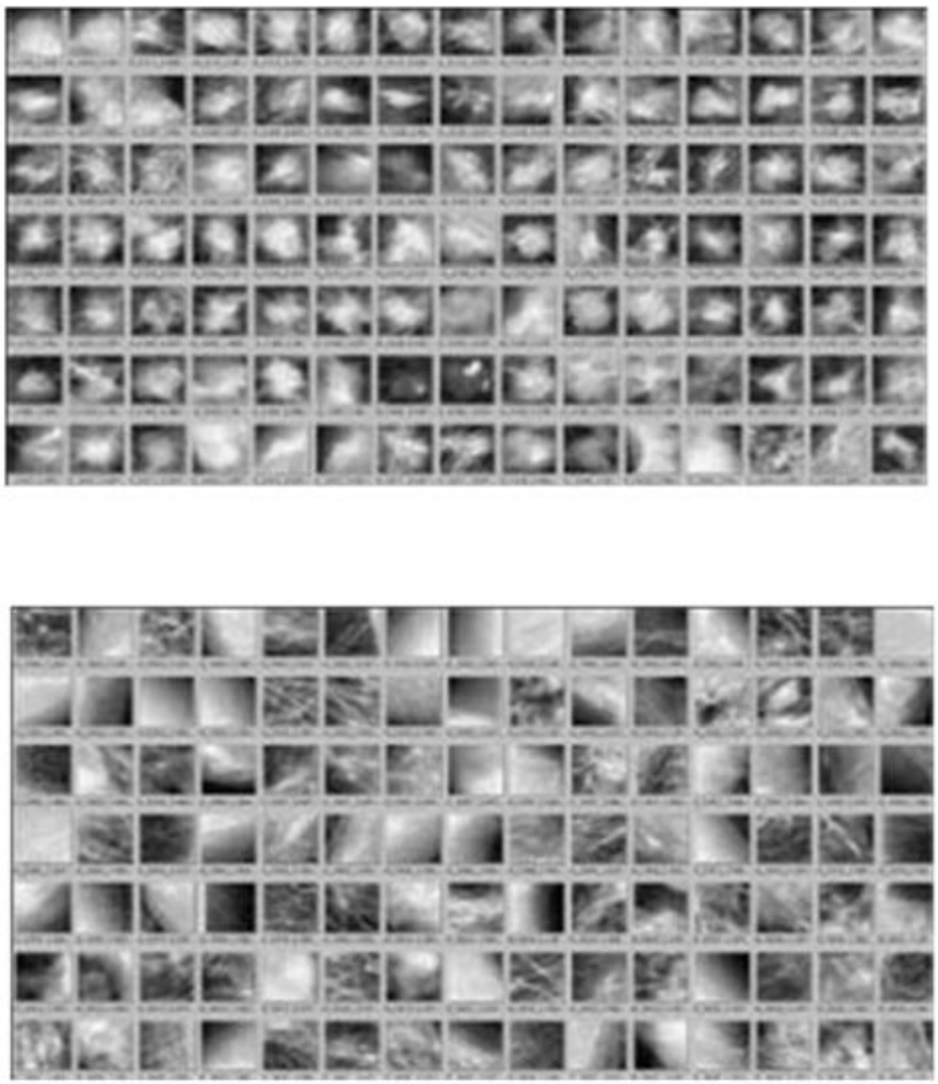


Figure 4. Training examples

The *Accu*Detect CAD software is able to detect areas suspicious for possible calcifications and/or soft tissue densities including architectural distortions, asymmetric densities, focal asymmetries, and suspect opacities with a dense core or spiculated masses.

Results are displayed on a computer monitor for review by a radiologist. The radiologist first reviews each case in the conventional manner, following her or his existing procedures of clinical practice. Then the radiologist uses Parascript® *Accu*Detect CAD to re-examine the case utilizing the information supplied by the CAD system before making a final assessment for the case.

Marks are placed at the region where the suspicious lesion is detected. The *Accu*Detect CAD software produces two types of marks: soft tissue density and calcification marks. A soft tissue density is marked by an oval. A radiologist is instructed to carefully consider the area in and around a soft tissue mark for the possibility of a soft tissue density. A calcification area is marked by a rectangle. A radiologist is instructed to carefully consider the area in and around a calcification mark for the possibility of a cluster of calcifications.

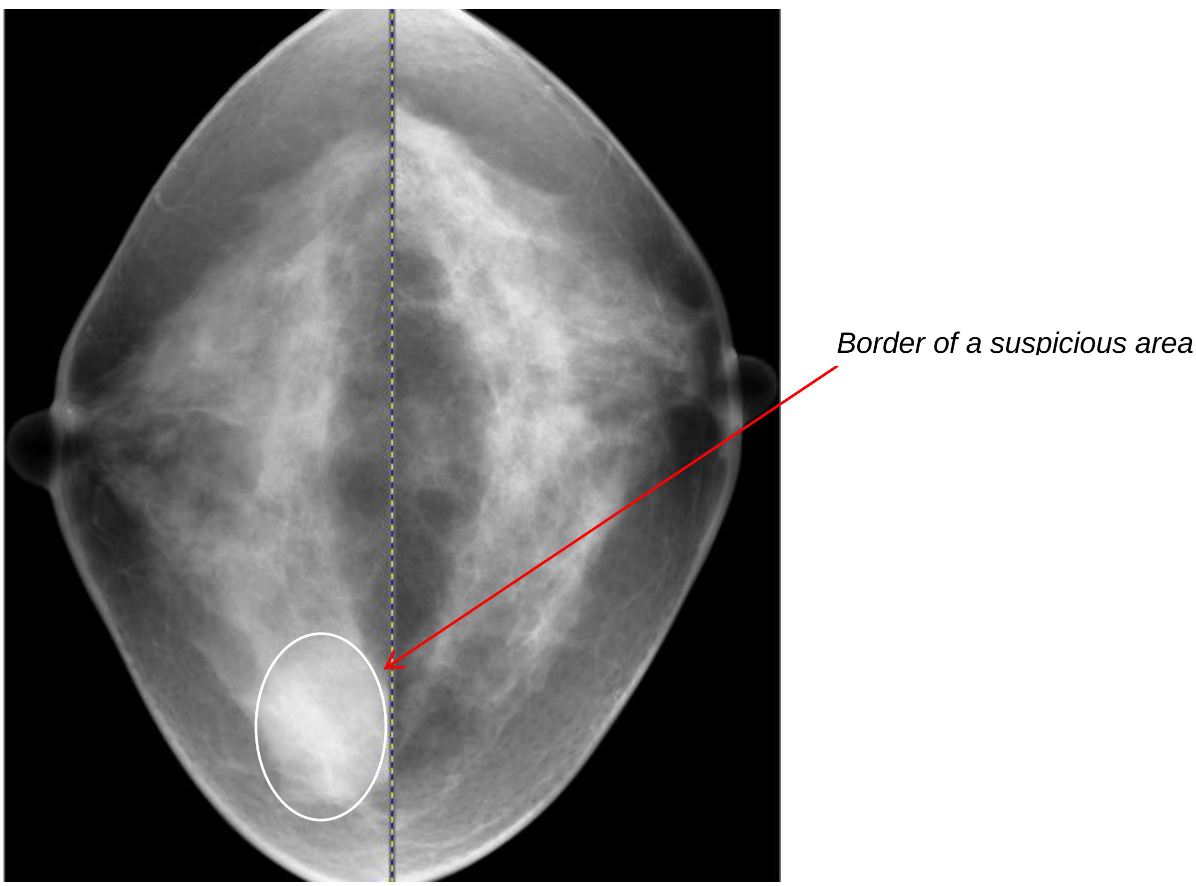


Figure 5. Soft tissue densities are marked by ovals.

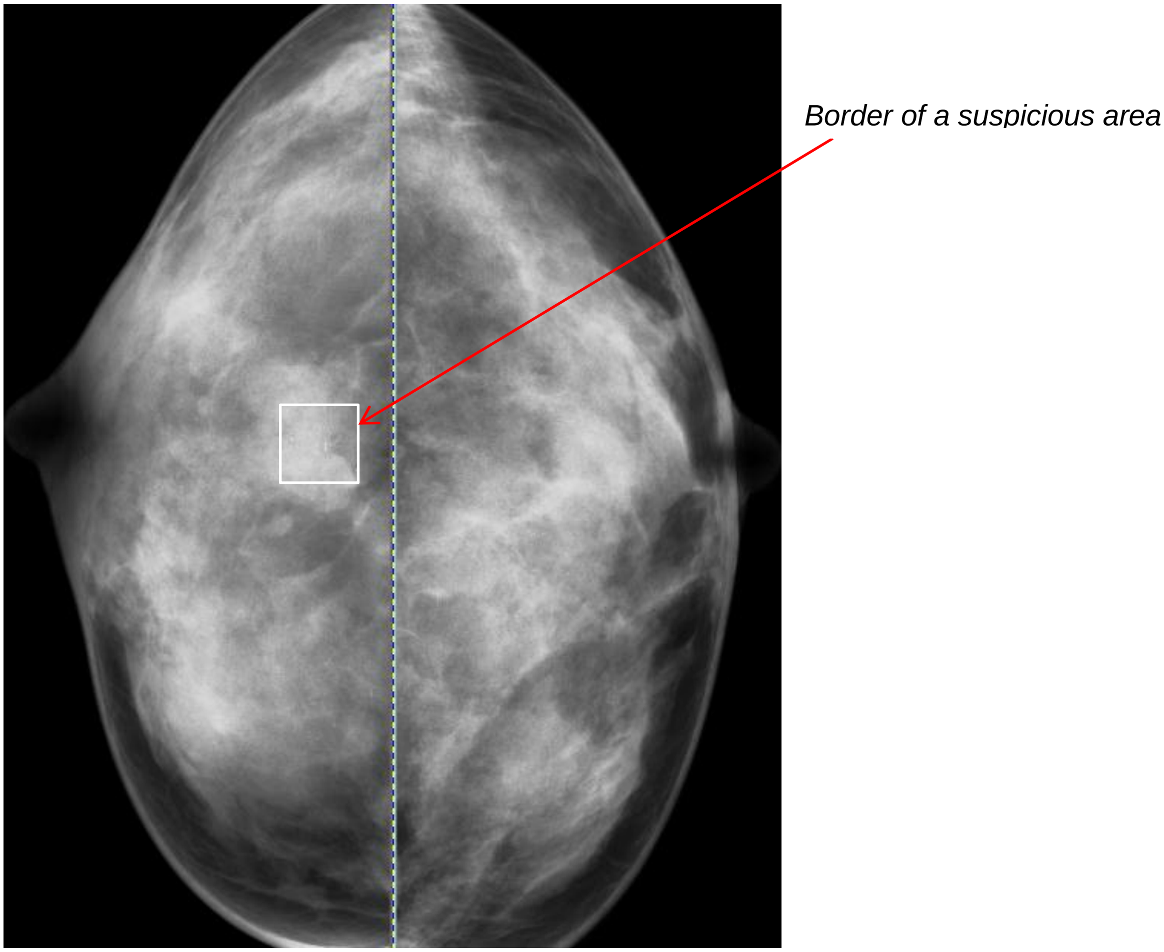


Figure 6. Calcifications are marked by rectangles.

6.1 Description of Detection Principles

6.1.1 Detection of Soft Tissue Densities

- *Accu*Detect can detect soft tissue densities with a diameter between 5mm and 50 mm.
- The automatic detection of soft tissue densities can be hampered by the wide diversity of their shape, size and subtlety.
- Due to the great variety of soft tissue densities, it is extremely difficult to get a common set of features effective for every kind of soft tissue density.
- Therefore, *Accu*Detect® algorithms automatically learn to detect the soft tissue densities by the examples presented to them during the training phase.

6.1.2 Detection of Calcifications

- *Accu*Detect CAD software can detect calcification clusters consisting of several calcifications with size between 0.1 mm and 0.8 mm in diameter within 2 cm^2 area.
- The algorithms (recognizers) rely on properties such as size, shape and contrast when searching for individual calcifications.

- The training phase enables the CAD to learn through presented examples.

6.1.3 Diagnosis

- The *Accu*Detect software should be considered as an aid to the detection of suspect regions, not as an aid to the interpretation or diagnosis of observed regions.
- *Accu*Detect® CAD selects the suspect regions, according to their visual appearance: regions marked are the most similar to the examples used during the training.
- The system can assist the radiologist in minimizing observational oversights by identifying regions that may warrant a more meticulous review.

Below are a few examples that demonstrate how *Accu*Detect® locates lesions on mammogram images.

6.1.3.1 Soft Tissue Densities

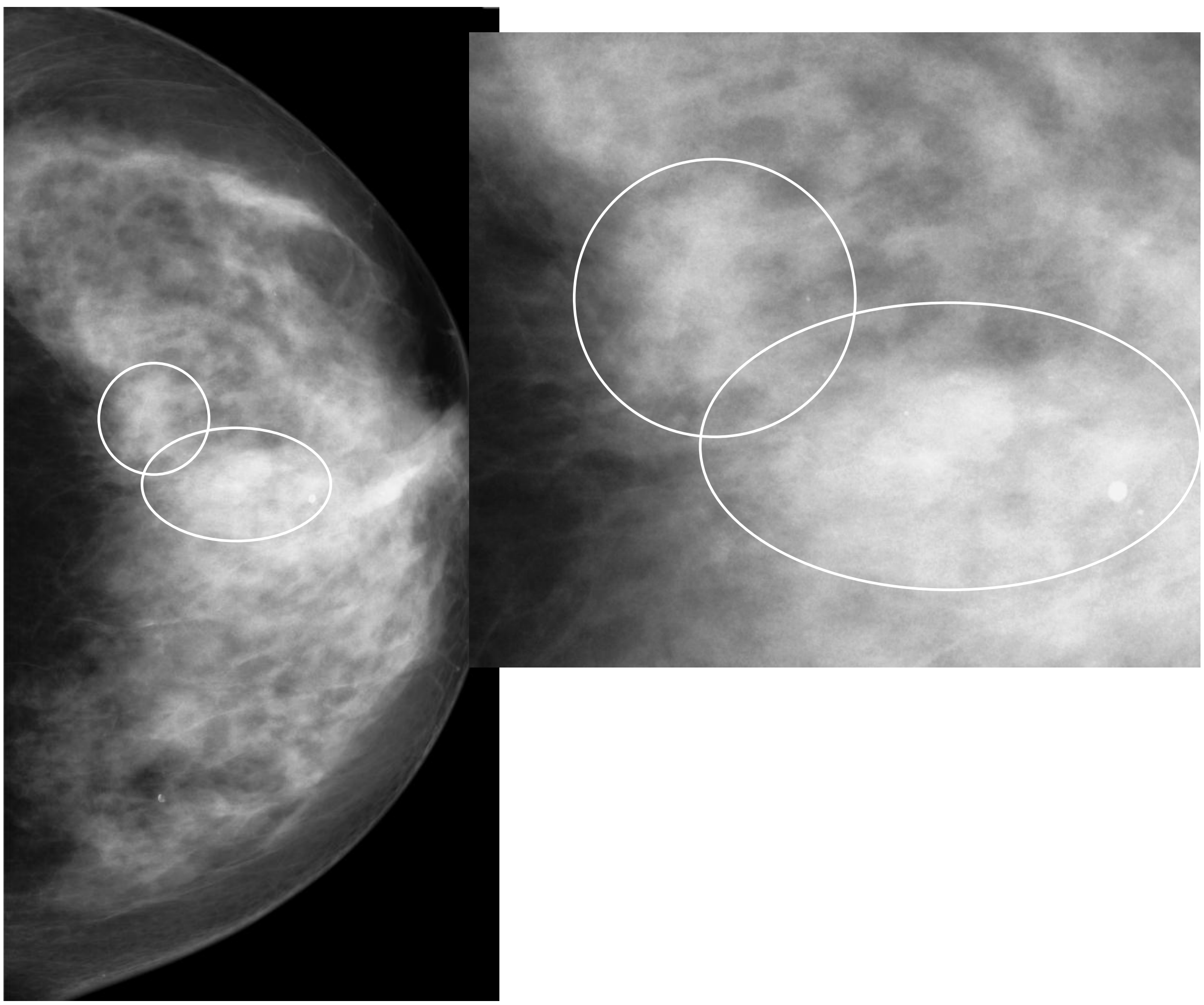
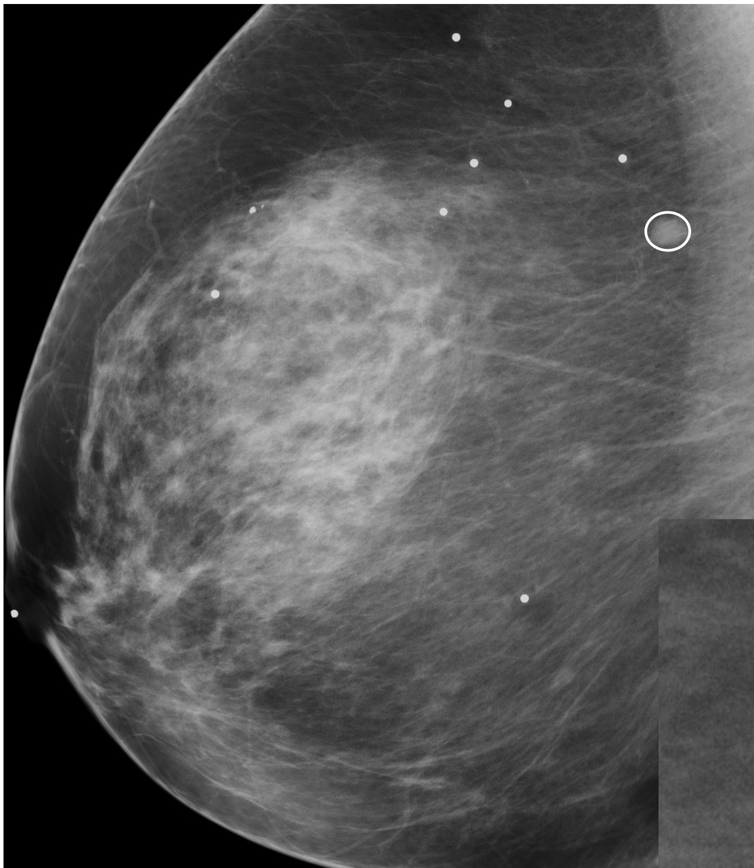


Figure 7. Non-spiculated mass with obscured margins found by AccuDetect® CAD .



A radiologist classified this case as normal. At first glance it looks like an intramammary lymph node but CAD marked this area as suspicious for soft tissue density. In a year a biopsy-proven cancer was diagnosed in the same area.

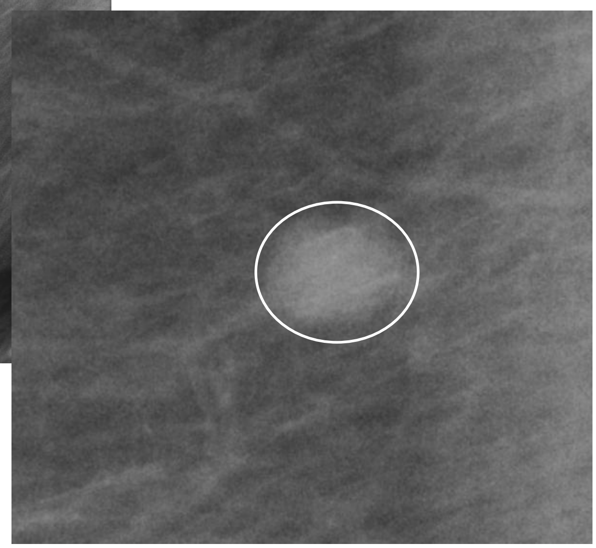


Figure 8. Prior of a cancer case.

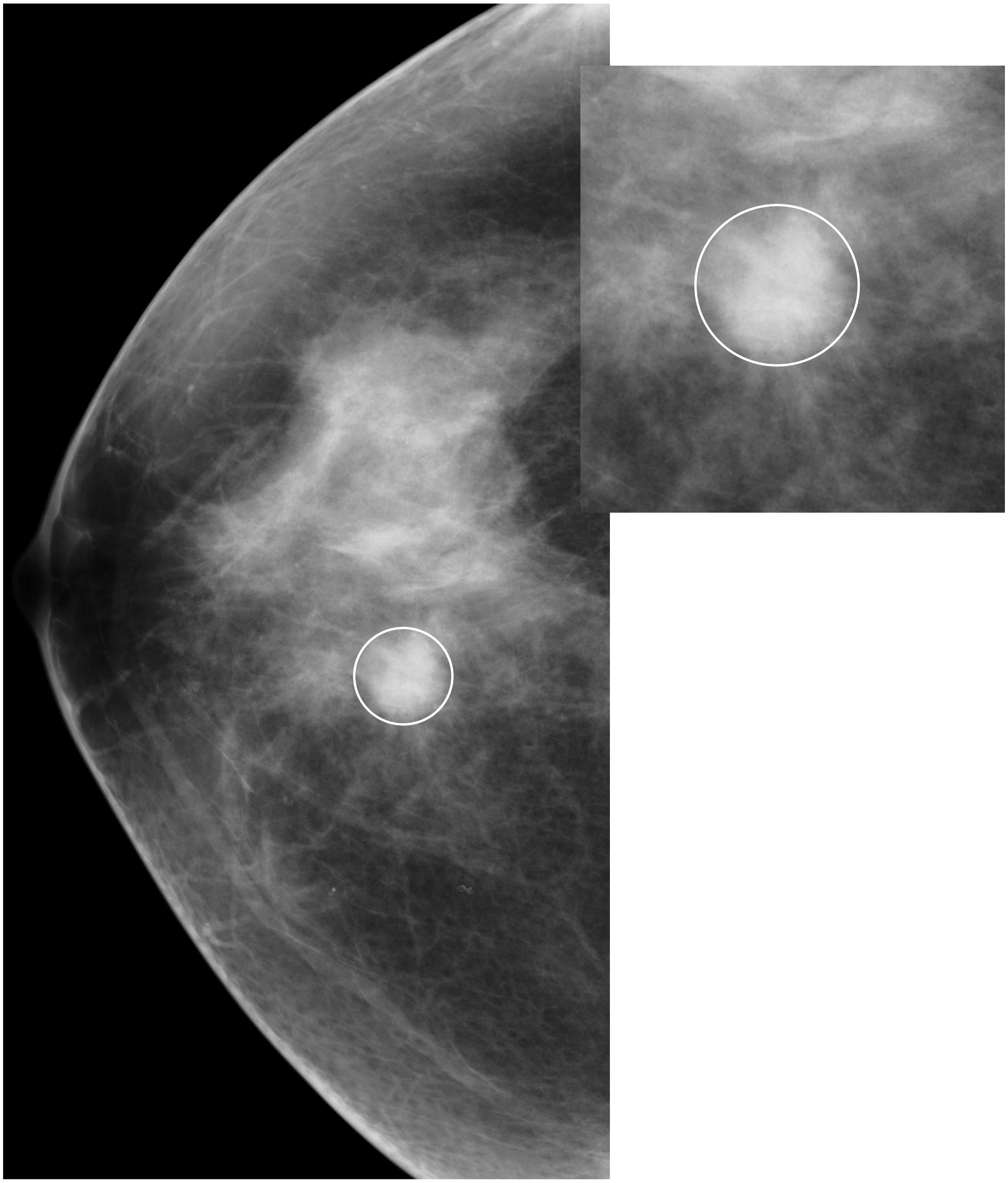


Figure 9. Spiculated mass found by *Accu*Detect ® CAD.

Figure 10. Irregular mass found by *Accu*Detect ® CAD.

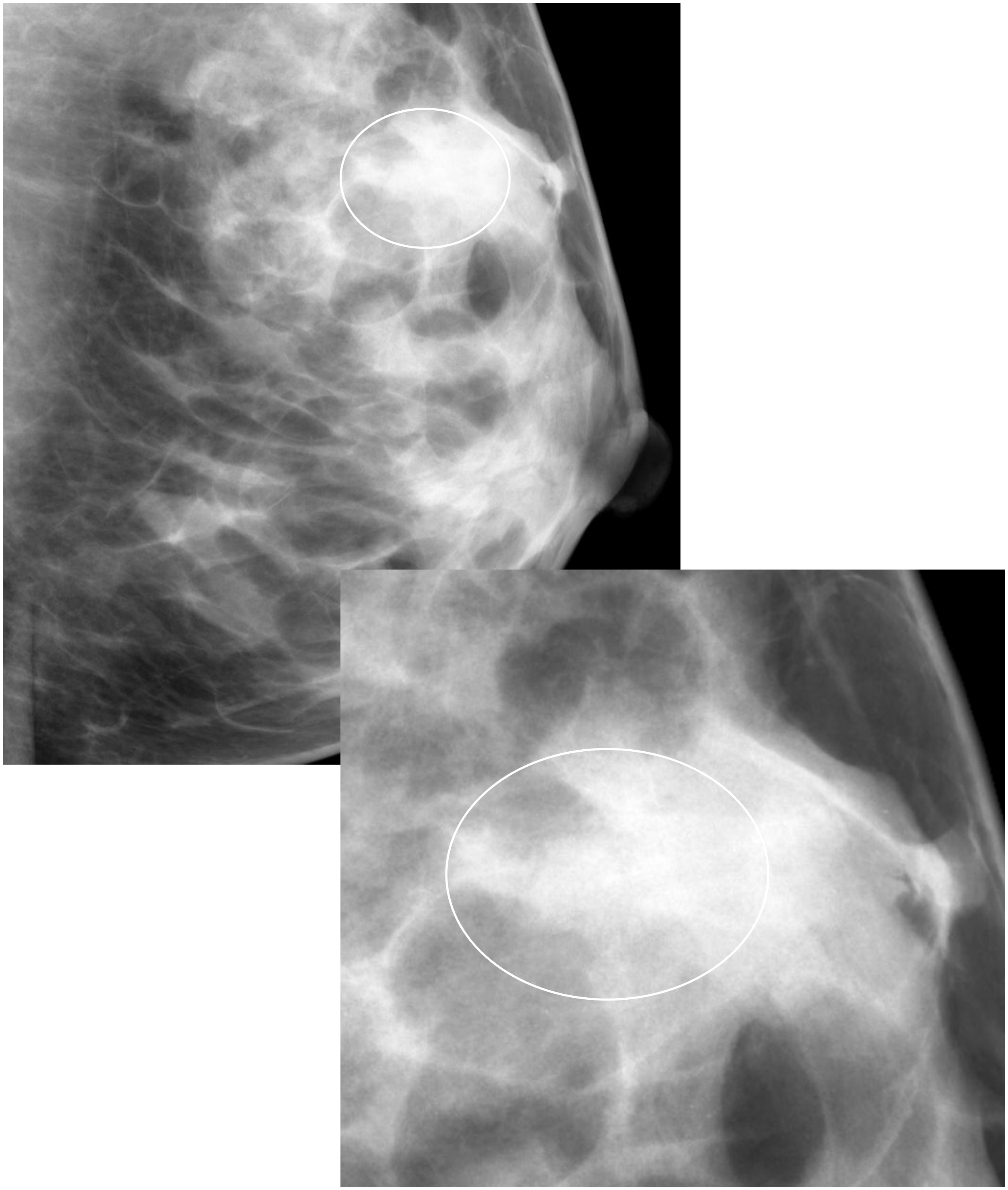


Figure 11. Architectural distortion found by *Accu*Detect ® CAD.

6.1.3.2 Calcifications

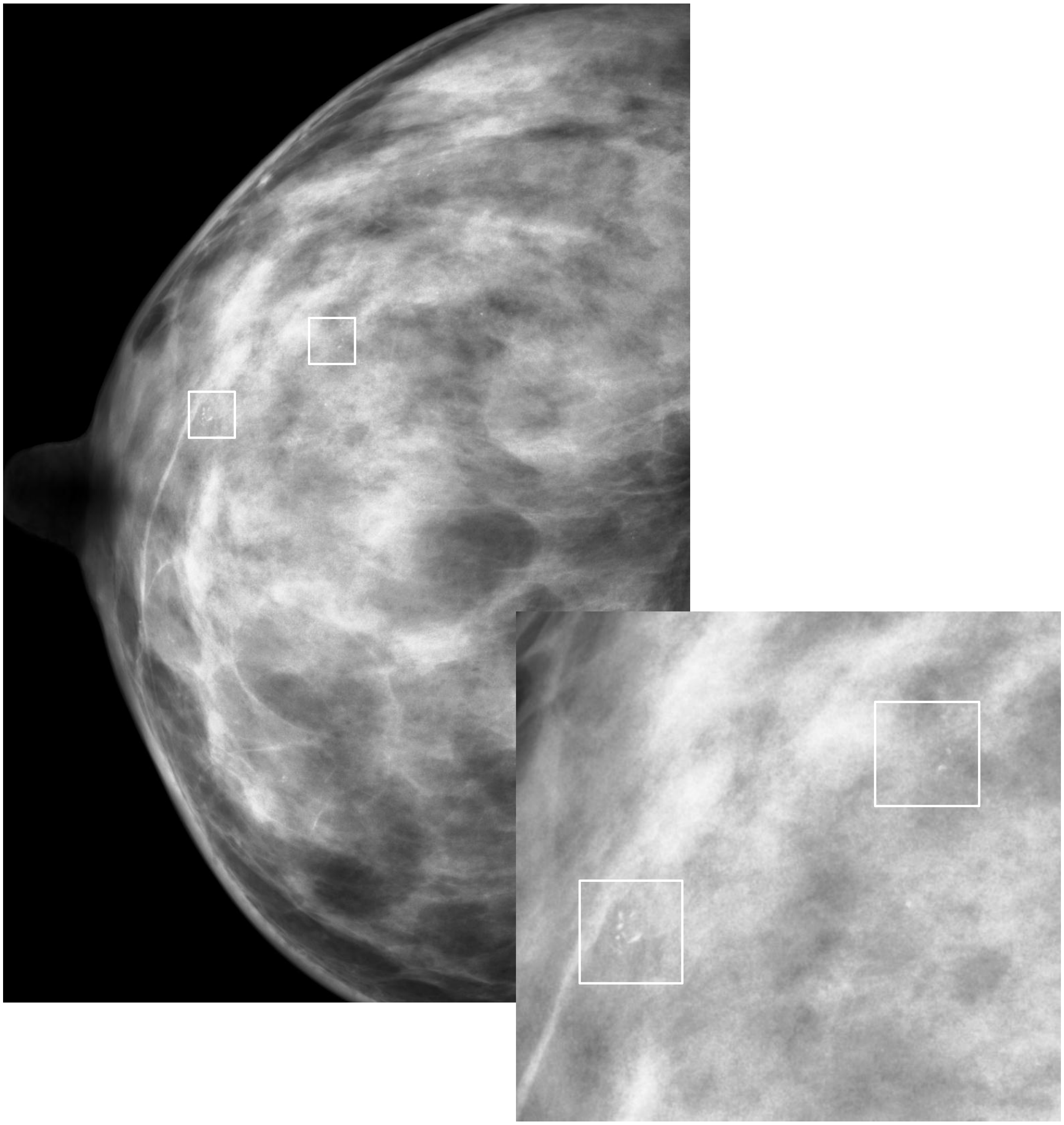


Figure 12. Calcification cluster found by *Accu*Detect ® CAD.

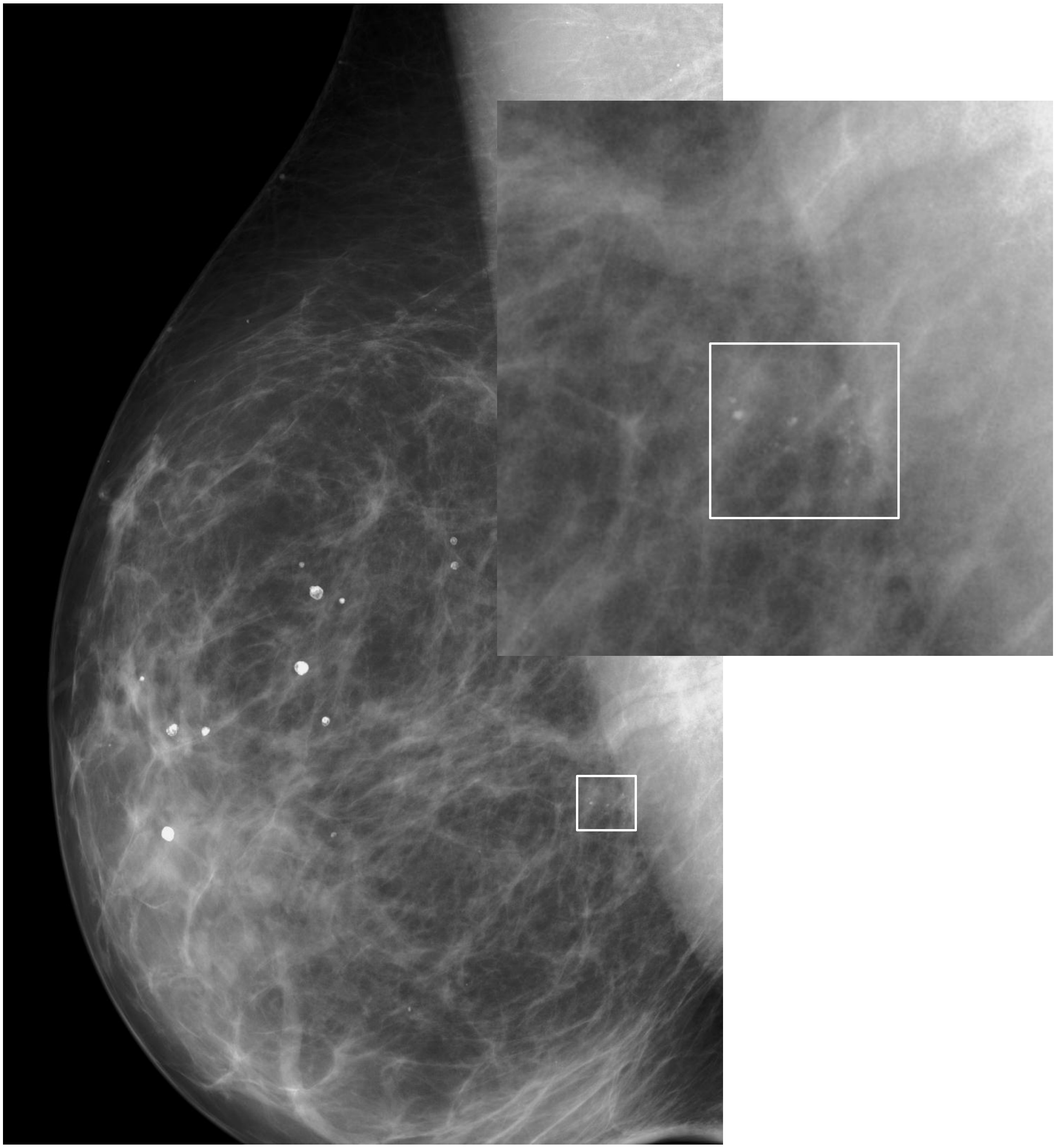


Figure 13. Heterogeneous calcifications found by *Accu*Detect ® CAD.

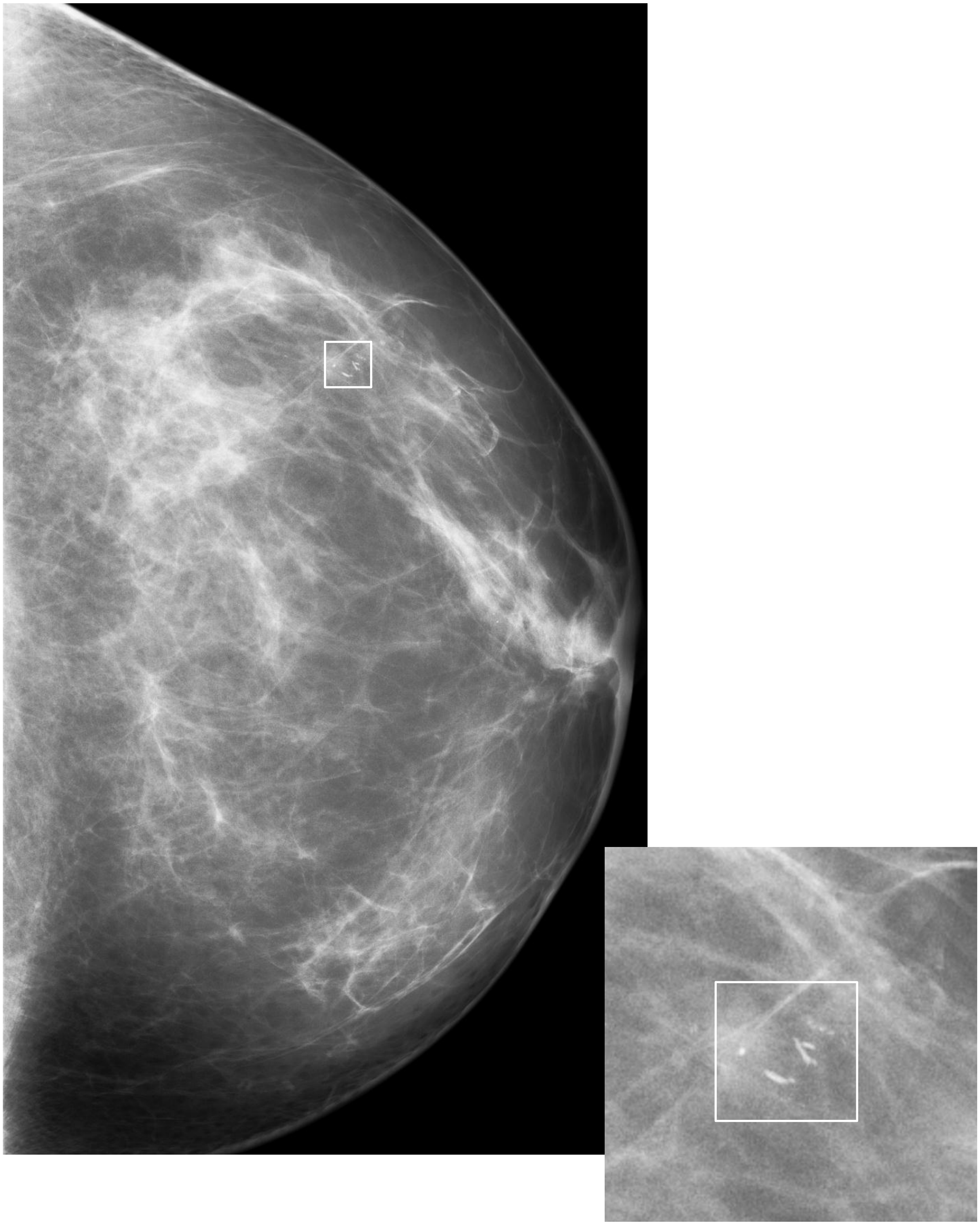


Figure 14. Branching calcifications found by *Accu*Detect ® CAD.

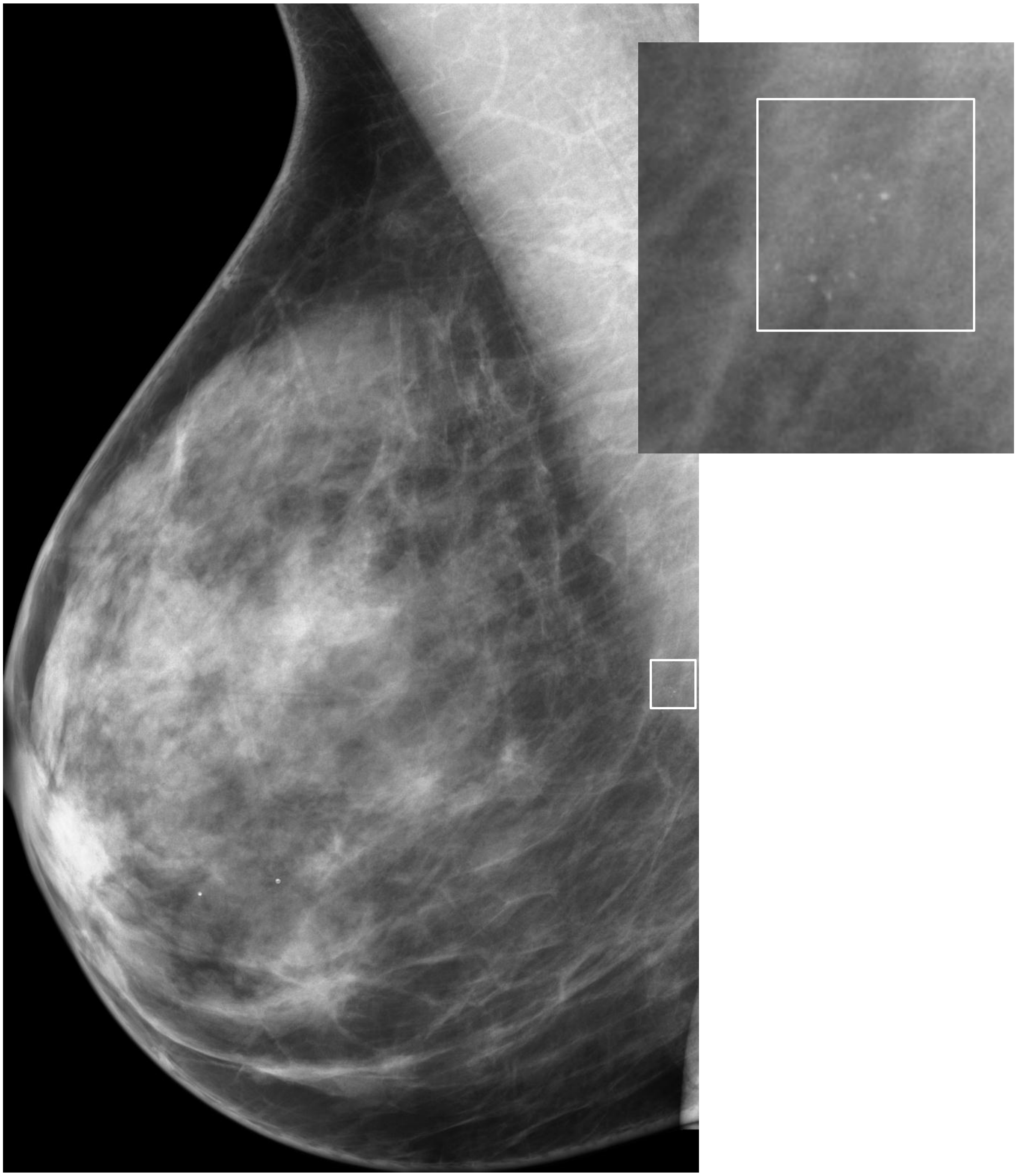


Figure 15. Cluster of heterogeneous calcifications found by *Accu*Detect ® CAD.

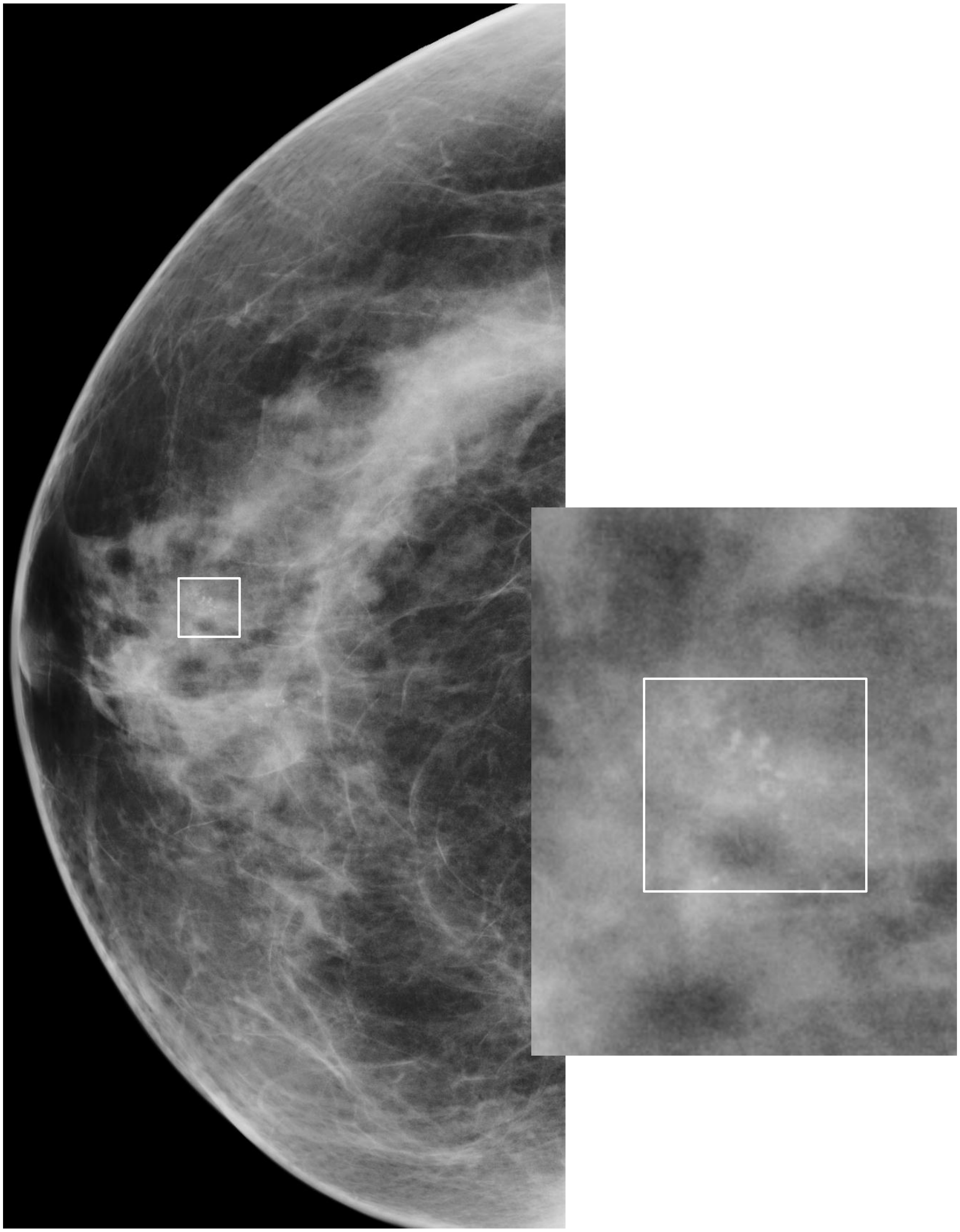


Figure 16. Cluster of pleomorphic calcifications found by *Accu*Detect ® CAD.

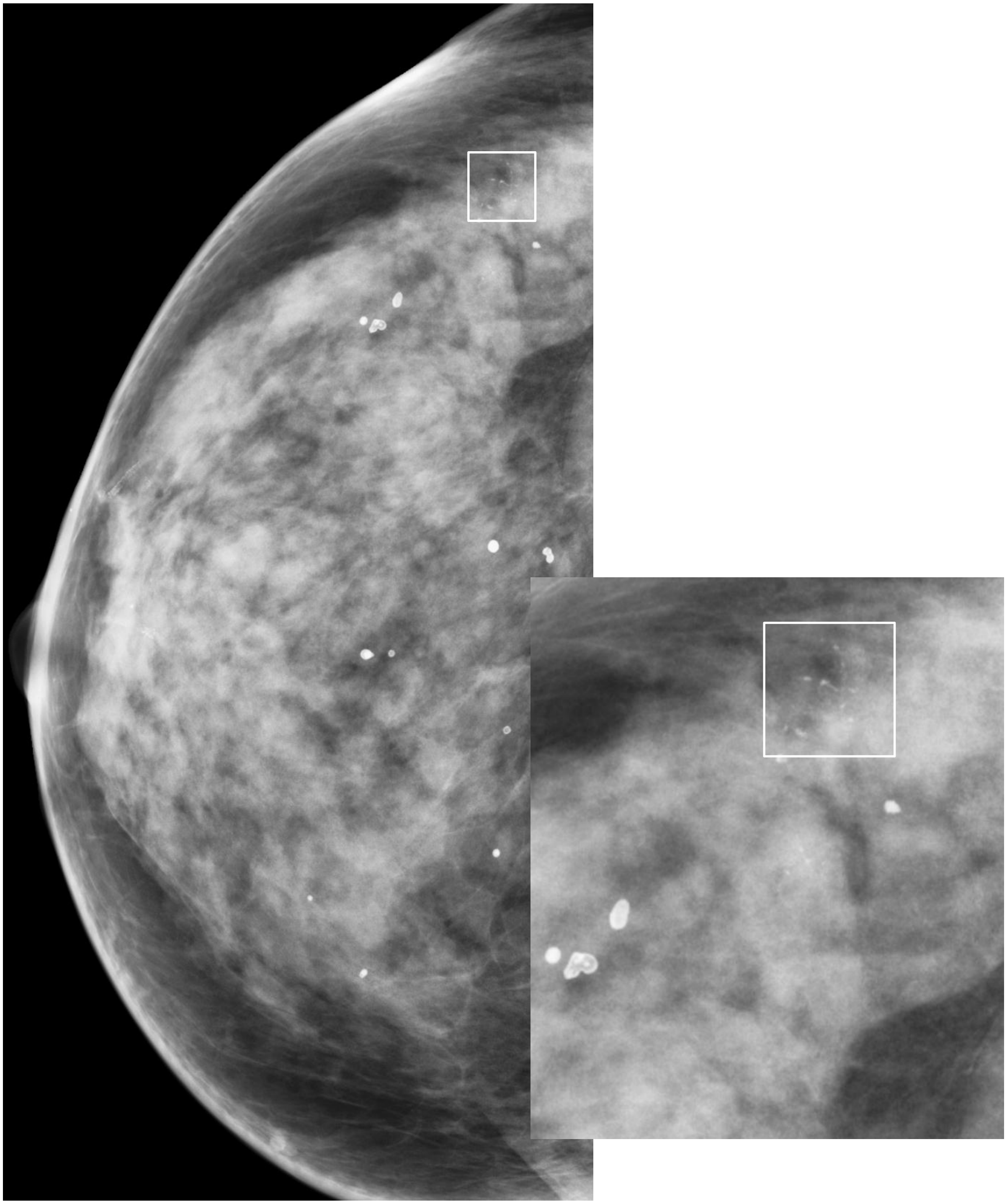


Figure 17. *Accu*Detect ® CAD marked calcification cluster and did not mark a benign macro-calcifications.

6.1.3.3 Soft Tissue Densities and Calcifications

Below are a few examples of soft tissue density and calcification marks on calcified mass lesion detected by *Accu*Detect ® CAD.

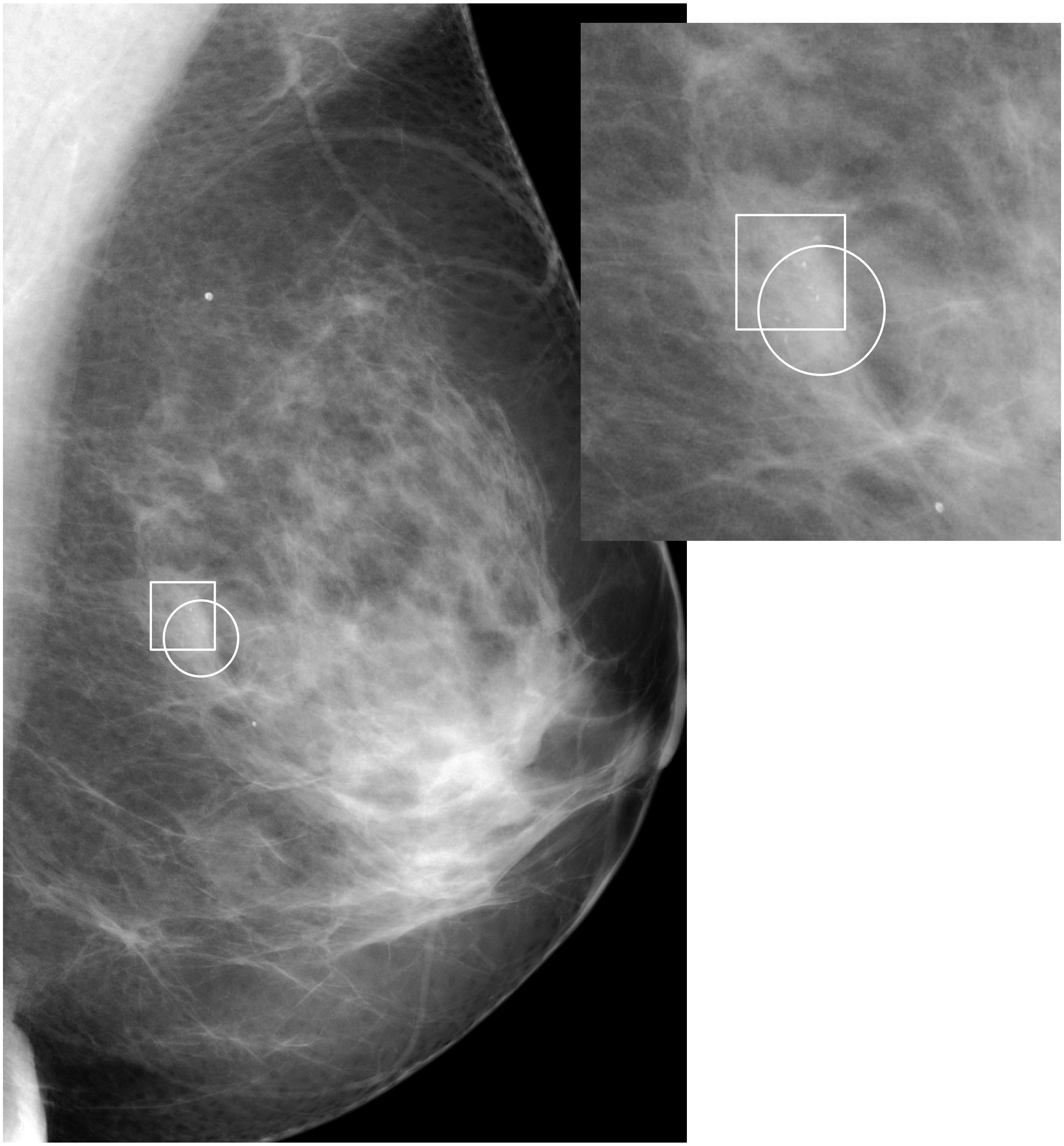


Figure 18. Example 1 - soft tissue density and calcifications.

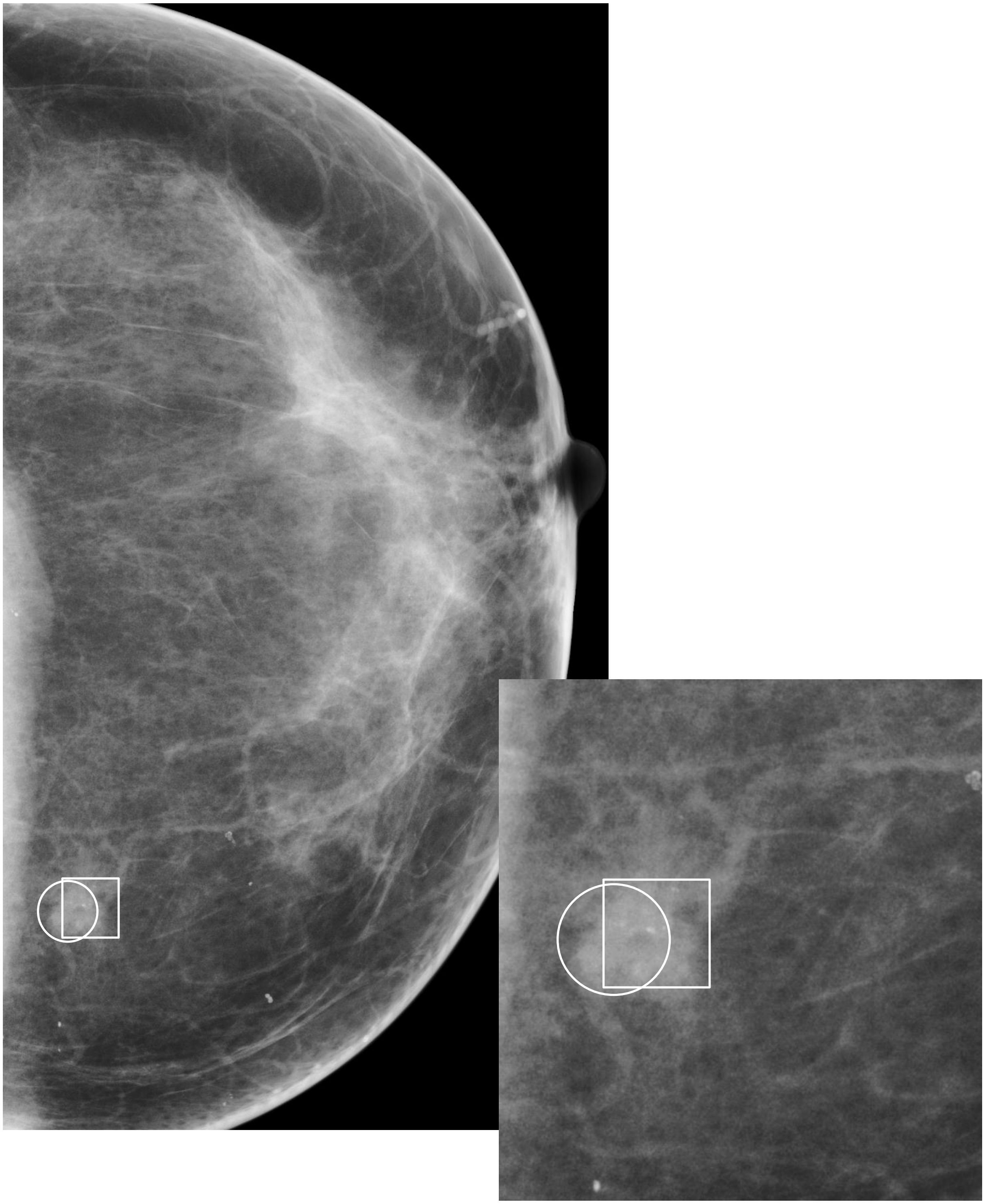


Figure 19. Example 2 - soft tissue density and calcifications.

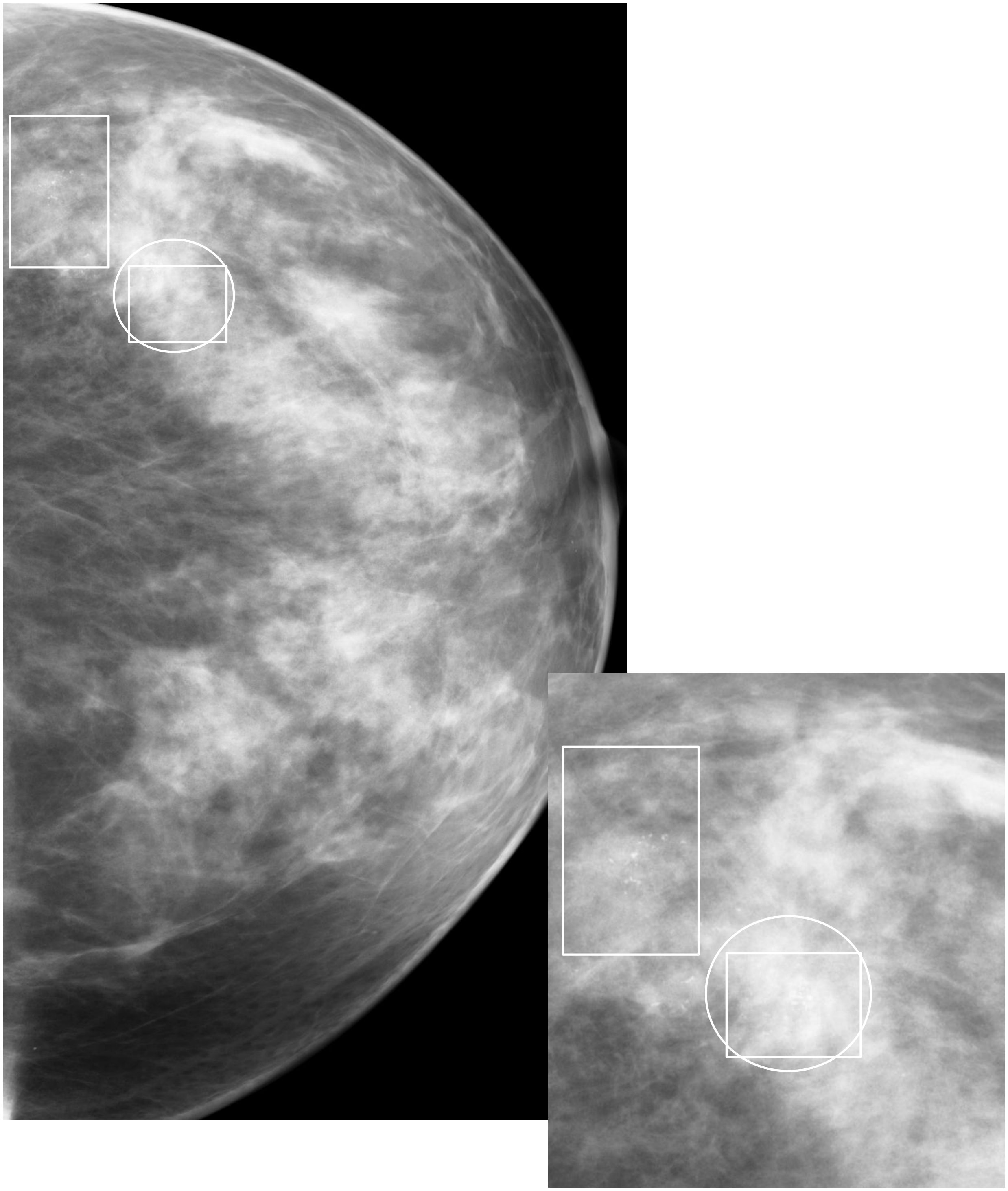
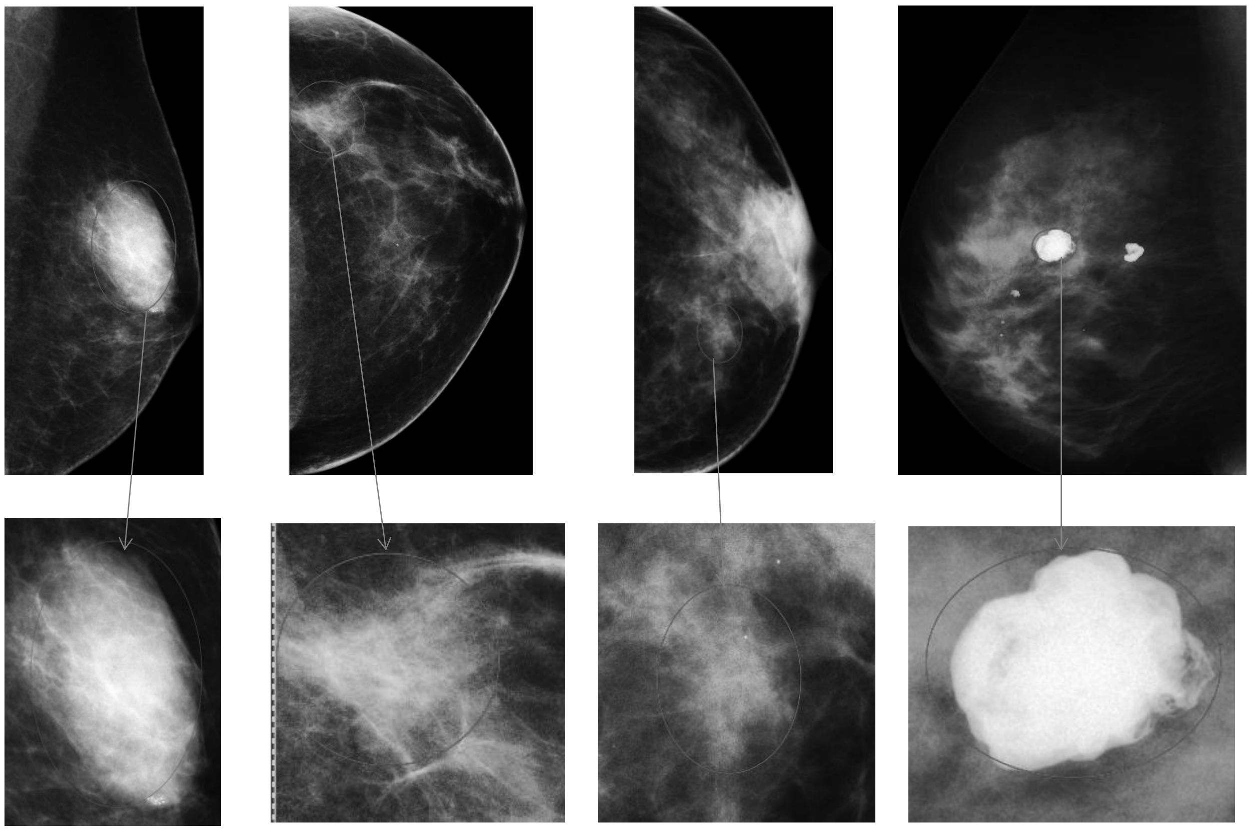


Figure 20. Example 3 - soft tissue density and calcifications.

Not all areas identified by *Accu*Detect® CAD are related to malignant lesions. *Accu*Detect® CAD marks many suspicious areas that do not represent cancer. Such marks are false positives. The user must always apply interpretative skills when reviewing the marked areas.

6.1.4 False Positive Soft Tissue Densities

Here are some typical examples of false positives:



Benign mass

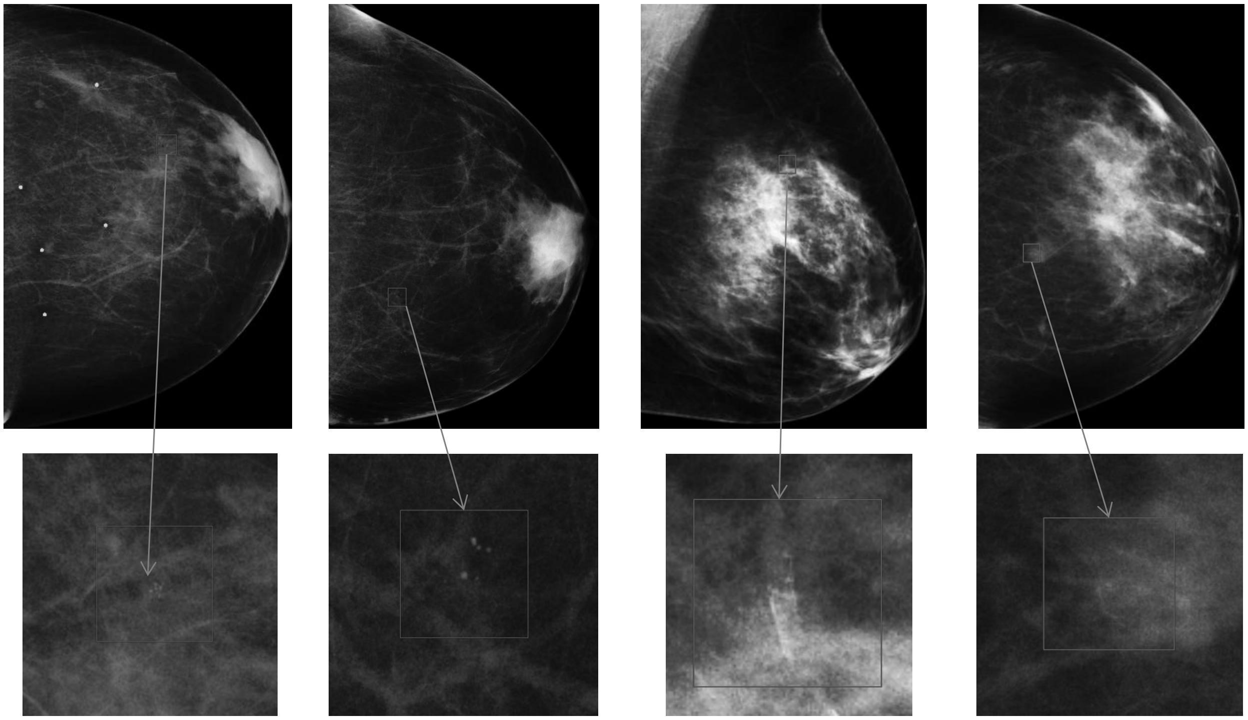
Parenchymal structure

Superposition of normal tissue

Large dystrophic calcifications marked as mass

Figure 21. Soft tissue densities - examples of false positives.

6.1.5 False Positive Calcifications



Cluster of benign calcifications | Benign punctuate calcifications | Vascular calcifications | Quantum image noise

Figure 22. Calcifications - examples of false positives.

6.2 Technologist Training Requirements

Technologists must be able to correctly operate the *Accu*Detect® CAD system. Technologists must demonstrate appropriate knowledge and skills in the following items:

- Identify the intended use of the CAD Station;
- Identify CAD Station warnings and cautions;
- Initialization and rebooting of the CAD Station;
- HASP license key requirements;
- Successfully log in to the CAD Station and Viewer Station;
- Identify the elements and functions of the CAD Screen;
- Display the CAD Station licensing information;
- Identify the elements and functions of the interfaces for CAD Station and Viewer Station;
- Demonstrate how to manually select images for CAD processing;
- Demonstrate how to filter completed cases by selecting a date or range of dates;
- Identify the purpose of the Loader Screen;
- Demonstrate how to load cases and delete cases;
- Demonstrate how to change the image display order;
- Demonstrate how to change the default multi-viewer panel settings;

- Demonstrate how to clear all cases stored in the viewer panels;
- Identify the service and maintenance requirements for the CAD Station and Viewer Station;
- Review Station should be set up to display CAD marks according to characteristics (shape, size) specified in the Structured Report.

6.3 Radiologist Training Requirements

Radiologists must have a full understanding of the *Accu*Detect® CAD system functions and capabilities including the following:

- Identify the intended use of the *Accu*Detect® CAD;
- Identify *Accu*Detect® CAD warnings and cautions;
- Identify the key performance characteristics of *Accu*Detect® CAD;
- Be aware how to view CAD marks on the review station (may vary depending on the Review Station);
- Identify the shape of a calcification CAD mark;
- Identify the shape of a soft tissue density CAD mark.

6.4 *Accu*Detect CAD System Operation

*Accu*Detect® CAD processes images received from mammography systems, looks for characteristics commonly associated with cancer - specifically, calcifications and soft tissue densities and detects suspicious areas that require further investigation. The algorithm provides results based on the analysis of images (mammographic views) assembled in cases. Although *Accu*Detect® CAD can process a case with any number of images its effectiveness has only been established for cases which consist of the four traditional mammographic views (Right CC, Left CC, Right MLO, Left MLO).

Recognition algorithm requires some time to process the images, so it may take up to one minute to display the results on the review workstation.

7 How to Contact Us

Parascript Customer Service is available to answer questions about business, pricing, upgrades, customization, and order status. Technical Support is available to answer questions about technology, integration, and troubleshooting. Contact us at:

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8 References

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